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ELLIS (cont'd)

ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND
RELATED MATTERS.

Hearing held
8th floor
180 Dundas Street West
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

P.S.A. Lamek, Q.C.

E.A. Cronk

Thomas Millar

Commissioner

Counsel

Associate Counsel

Administrator

Transcript of evidence
for

October 17, 1983

VOLUME 50

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ROYAL COMMISSION OF INQUIRY INTO CERTAIN
DEATHS AT THE HOSPITAL FOR SICK CHILDREN
AND RELATED MATTERS.

Hearing held on the 8th Floor,
180 Dundas Street West, Toronto,
Ontario, on Monday, the 17th day
of October, 1983.

THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner
THOMAS MILLAR - Administrator
MURRAY R. ELLIOT - Registrar

APPEARANCES:

E. CRONK	Commission Counsel
D. HUNT) L. CECCHETTO)	Counsel for the Attorney- General and Solicitor General of Ontario (Crown Attorneys and Coroner's Office)
S. GRANT	Counsel for The Hospital for Sick Children
B. PERCIVAL, Q.C.) D. YOUNG)	Counsel for The Metropolitan Toronto Police
K. CHOWN	Counsel for numerous Doctors at The Hospital for Sick Children
F. KITELY	Counsel for the Registered Nurses' Association of Ontario and 35 Registered Nurses at The Hospital for Sick Children

(Cont'd)



APPEARANCES: (Continued)

D. BROWN

Counsel for Susan Nelles -
Nurse

G. R. STRATHY)
P. DODDS)

Counsel for Phyllis Trayner -
Nurse

A. ARNOLD

Counsel for Janet Brownless -
R.N.A.

B. KNAZAN

Counsel for Mrs. M. Christie -
R.N.A.

S. LABOW)
P. CONNELLY)

Counsel for Mr. & Mrs. Gosselin,
Mr. & Mrs. Gionas, Mr. & Mrs.
Inwood, Mr. & Mrs. Turner, and
Mr. & Mrs. Lutes (parents of
deceased children)


W.W. TOBIAS

Counsel for Mr. & Mrs. Hines
(parents of deceased child
Jordan Hines)

J. SHINEHOFT

Counsel for Lorie Pacsai and
Kevin Garnet (parents of
deceased child Kevin Pacsai)

VOLUME 50



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A/EMT/ak

1
2 ---Upon commencing at 10:00 a.m.

3 DR. GRAHAM ELLIS, Resumed

4 THE COMMISSIONER: I think we were
5 at you, Mr. Brown, weren't we?

6 MR. BROWN: Yes, if Miss Chown has
7 no questions.

8 MS. CHOWN: No, thank you.

9 THE COMMISSIONER: I am not too sure
10 that this is your client. Am I right or am I wrong?

11 MS. CHOWN: Yes, that is quite right.

12 THE COMMISSIONER: I am right that
13 he is or that he isn't?

14 MS. CHOWN: You are right that he is
15 not.

16 THE COMMISSIONER: Yes.

17 MR. BROWN: If I may, Mr. Commissioner,
18 make a request through you to Commission Counsel:
19 in the next few weeks we will be hearing from
20 Drs. Phillips and Cimbura.

21 If I recall when Dr. Cimbura first
22 appeared before the Commission he gave a number of
23 undertakings to provide to counsel information
24 concerning tests that were performed. It would be
25 of great assistance if we could have that data
several days in advance of his testimony. We have



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been fortunate with Dr. Ellis that we have had --

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THE COMMISSIONER: You can't have it
for several days because he is slotted for Wednesday.

5

Is that right?

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MS. CRONK: I think it is quite
possible that he can be reached as early as Wednesday
this week.

8

9

THE COMMISSIONER: Yes.

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MS. CRONK: But I will certainly
raise the matter with Mr. Lamek and whatever documenta-
tion he now has we will try to get it.

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16

MR. BROWN: And similarly I don't
know when Dr. Phillips will be called but I understand
Dr. Phillips conducted a study and if it is possible
to have that study a day or two in advance of his
testimony for review it will certainly facilitate
cross-examination.

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18

THE COMMISSIONER: Okay. I think we
got an affirmative nod from Miss Cronk.

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MS. CRONK: Sorry. We will look into
that as well.

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CROSS-EXAMINATION BY MR. BROWN:

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Q. Dr. Ellis, if I may review
with you very briefly the radioimmunoassay procedure
which you adopted. My understanding is that this



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procedure uses essentially three sets of tubes.

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The first set of tubes would contain standards which you obtain from a manufacturer; the second set of tubes would contain controls which you also obtain from the manufacturer, and the third set of tubes contain the specimen of interest from the patient which you intend to assay. Is that correct?

9

10

A. That is right, yes.

11

12

Q. And standards and the control both contain known quantities of digoxin.

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A. Known quantities? Yes.
Q. In the sense that the standards, if I understand you have five different standards, each of which contains a certain amount of digoxin, and the controls similarly if I recall there are three controls which you use which contain levels of 1.0, 2.0 and 2.8 nanograms per millilitre of digoxin. Is that accurate?

19

20

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A. You mean now or in general?

Q. No, the particular time that we are considering back in the early part of 1981..

A. Yes. Approximately, okay.

Q. If I recall with respect to the controls when you originally appeared before this



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hearing you indicated that at that time you obtained your controls from the Ortho Company, and that there were three levels in the controls.

5

A. Yes.

6

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Q. 1.0, 2.0 and 2.8. Am I correct on that?

8

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10

11

A. I haven't seen that - those pieces of paper since I presented that evidence or at least I haven't looked at them in an attempt to remember them, but the general ideas that you are trying to get across are approximately correct.

12

13

14

Q. Well I can refer your counsel to Volume 8, page 822 of your testimony where perhaps at that time you had the more precise information.

15

16

A. Yes.

17

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Q. Those were the figures I was able to cull from your testimony.

A. Yes.

23

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Q. Now it is my understanding that the tests that you run, you add the antibody and the labelled digoxin to each of those sets of tubes. You then run the assay. You attempt to separate a portion of each tube, and by use of charcoal --

A. Yes.

Q. And then you take the separated



1
2 portion from each tube and you subject it to a gamma
3 counter test. Is that correct?

4 A. Yes.

5 Q. And then at the end of the day
6 for both the standards for the controls and for the
7 patient sample you will have a variety of gamma
8 counter readings?

9 A. Yes, that is correct.

10 Q. And it is my understanding that
11 the standards are then used to plot a curve or a
12 graph; is that correct?

13 A. Yes. By computer.

14 Q. By computer?

15 A. Yes.

16 Q. And in effect you would have
17 with the standards five tubes containing known
18 quantities of digoxin; you would have for each of
19 those tubes a gamma counter reading?

20 A. Yes.

21 Q. You would then be able to
22 correlate the gamma counter reading with the known
23 amount of digoxin thereby plotting a graph?

24 A. Yes.

25 Q. Is that accurate?

A. Yes.



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Q. And once you have plotted the graph or using the standards you are then able to take the patient sample and again for each patient sample you would obtain a gamma counter reading; is that correct?

7

A. That is correct, yes.

8

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Q. So you can then simply take a gamma counter reading X for a particular patient tube, locate that on the graph and get a corresponding digoxin level; is that correct?

11

A. Yes. By computer.

12

13

14

15

Q. Yes, by computer. The controls I understand are used to verify the accuracy of the graph that you would obtain by using the standards; is that correct?

16

A. Yes. To verify accuracy is a little strong.

17

18

Q. Well --

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20

A. But it is to give you a feel for whether the patient results you are producing are correct or not.

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Q. And of course the correctness of the patient results depends upon the accuracy of the curve that you have been able to develop using these standards?



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A. Yes.

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Q. Is that correct?

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A. Yes, that is correct.

5

Q. And you have a second set of

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tubes, the controls which contain known amounts of digoxin, so you are then able to take, for example, a control tube containing 1.0 nanograms of digoxin, take its gamma counter reading, and theoretically it should plot on the curve where the standard is given a 1.0 reading; is that correct?

10

11

A. Approximately, yes.

12

Q. And similarly with the control

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containing 2.0 nanograms of digoxin, the gamma counter reading you obtain for that theoretically should plot at the 2.0 reading on the curve which you obtain by using the standards; is that correct?

15

16

A. Approximately correct, yes.

17

Q. And inevitably there would

18

probably be some deviations?

19

A. Yes.

20

Q. For example, you might have a

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control which should give a reading of 1.0 when in fact the reading you get by plotting it on the curve is in the neighbourhood of 1.1; is that correct?

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A. Yes.

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Q. And your concern I imagine would be with the degree to which the readings you get for the controls may vary from the graph that you have plotted?

A. Yes.

Q. And is there an acceptable degree of variation that you used during the course of these assays for your controls? For example, if you have a control of 2.0 and you plotted it on the graph and it gave a reading of 2.3. Would that be within an accepted range of deviation for you?

A. Depending on the circumstances. You would come to some judgmental decision on the events of that particular day, and the technologist would come to one decision and then if that was reviewed by myself I may come to the same or a different decision.

You cannot take a single result on a single control on a single day and say what decision you will make. You will look at a number of factors, as I tried to explain previously when I was before this Commission in deciding whether you accept these results or whether you don't.

Q. Well, would I be correct --

THE COMMISSIONER: Before you go on,



1
2 Mr. Brown, I don't know what this is leading to. You
3 perhaps weren't here, but initially the general
4 method was gone into and cross-examined upon when
5 Dr. Ellis was here, and these are supposed to be
6 particular readings that he was brought back for.

7 Now you may be leading up to something,
8 but even if you are shouldn't it have been done
9 initially rather than now?

10 MR. BROWN: Well, in fairness, I
11 wasn't asking questions then.

12 THE COMMISSIONER: No, no.

13 MR. BROWN: And I am now.

14 THE COMMISSIONER: But your client
15 was represented.

16 MR. BROWN: Yes. It is also my
17 understanding that the level of knowledge at that
18 time of the assays was perhaps not as great as it is
19 now.

20 THE COMMISSIONER: It was a great
21 deal greater. We were much concerned about the RIA
22 procedure at that time. But none of us have been think-
23 ing about it, just like Dr. Ellis, a great deal since. I
24 thought that was the purpose of dividing it up --

25 MR. BROWN: Well, it may well have
been --



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THE COMMISSIONER: And the general questions then and the particular questions now.

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But if we are going to have general questions --

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MR. BROWN: Well, I certainly intend - with respect, Mr. Commissioner, I would certainly just first like to lay the groundwork and intend to deal with the specifics.

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THE COMMISSIONER: All right.

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MR. BROWN: My reading of Dr. Ellis' testimony when he initially appeared indicated that this area was not touched upon.

12

THE COMMISSIONER: Well --

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MR. BROWN: It may be of significance and it may not be of significance but --

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THE COMMISSIONER: All right.

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MR. BROWN: But if this is the last time he is going to appear in this case I would at least like to be able to touch upon it.

18

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THE COMMISSIONER: I am afraid we can't even promise him that but it is certainly the last time for a while.

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How much longer are you going to go on on the procedure?

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MR. BROWN: I am at the nub of the issue right now, Mr. Commissioner.

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THE COMMISSIONER: All right. Let's
have it.

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MR. BROWN: Q. Dr. Ellis, turning to
control samples, if you have a control sample which
I believe you labelled as Control B which is supposed
to contain 2.0 nanograms per millilitre of digoxin,
and if at the end of the assays you have run, and
after you have plotted the graph, that control sample
is plotted at a 2.5 level on the graph, would I be
correct in saying that one still has a sample with
2.0 nanograms of digoxin in it but by virtue of
the shape of the graph one obtains a reading of 2.5?



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A. Are you referring to a specific instance, or is this a hypothetical discussion?

A. No, I'm ---

Q. Okay. Well, the reason that I was concerned about the exact wording that you are using, is that you are always referring to controls that contain a known amount of digoxin, and you implied that that was absolutely a definitive known amount of digoxin. In truth there is an amount of digoxin put into these samples, and these samples are assayed by a series of reference laboratories and by a series of procedures and values are obtained and sheets are prepared by the manufacturers and they are supplied to us, the people who use those controls, but there isn't a specific absolutely correct answer in a definitive sense, the kind of implication that you have.

Q. Well, simply speaking in and around the possibility then.

A. Okay.

Q. I have a control, and the claimed value for that control is 2.0, plotting it on the graph the graph indicates a reading of 2.5?

A. Yes.

Q. Is it possible then that the



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sample still contains only 2.0 nanograms per millilitre, but by virtue of the graph produced by the standards a reading of 2.5 nanograms per millilitre has been given?

A. Yes, it is possible.

Q. So the reading which you may obtain, referring it to the graph, would be 2.5 nanograms per millilitre, but in fact the amount of digoxin contained in the control may still only be 2.0 nanograms per millilitre?

A. That is correct, yes.

Q. Would it then be possible, Dr. Ellis, that if that is the case on a particular assay, if one was to take the gamma counter reading from a patient sample and plot that on the graph and obtain a reading of 2.5, that the actual amount of digoxin in that patient sample is not 2.5 but 2.0; would that be possible?

A. Well, it would be possible, yes.

Q. Well, perhaps to be clear, what I am trying to establish is that if you have a control mechanism to verify the reliability of the graph which you have plotted using the standards, and you are in a position where a sample that you think will give you a reading of 2.0 plots at a reading of 2.5,



B.4

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that it is possible if one is to plot a patient sample of 2.5, in fact there may only be 2.0 in the patient's sample, is that a possibility?

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A. It's a possibility, yes, I will put it no stronger than that.

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Q. Fine.

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A. We are dealing with hypothetical examples, but whether any individual batch is rejected on the basis of a single control result is a matter of discretion; and whether a batch is rejected or reported depends upon the form of the standard curve, the agreement between duplicates and the values of three controls and the duplicate values for the individual patient samples. So this is why ---

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16

17

Q. Well, if you were to get a situation where you do have a control of 2.0 which plots at 2.5, would you necessarily correct the graph to incorporate that discrepancy?

18

A. You mean on a single occasion?

19

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Q. On a single assay run, that's correct.

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A. Well, it would depend on other factors that I have just tried to explain, all the other factors that you may take into account as to how you might act in a hypothetical situation.



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Q. Very well. Could you then perhaps turn to the particulars and if I could refer you to page 24 of your assay book found at Tab 45 of the exhibits at the Preliminary Inquiry.

A. Tab?

Q. Tab 45.

A. Yes.

Q. At page 24, and referring to the results you obtained on March 16th, 1981, and on that day you have listed three controls, Control A, Control B and Control C. The values which you have listed for Control A is 1.2; the value for Control B is 2.5; and the value for Control C is 3.0. I take it that those numbers are numbers taken off the graph?

A. Yes.

Q. And in Control A the claimed value for the control is 1.0, and the reading in that case was 1.2; in Control B the claimed value of 2.0 and the reading is 2.5; and in Control C the claimed value is 2.8 and the reading is 3.0. So there is a slight discrepancy between the claimed values and the values as plotted on the graph which you have created by reference to the standards, is that correct?



B.5

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THE COMMISSIONER: Where are you
getting the claimed values did you say?

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MR. BROWN: The claimed values I was
taking from Dr. Ellis' previous testimony, Mr.
Commissioner.

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THE COMMISSIONER: Oh, I see, yes.

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THE WITNESS: Did that relate to
March 1981, the claimed values that I quoted on that
occasion?

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MR. BROWN: Q. The claimed values
that you quoted were simply the claimed values by
Ortho, and in fairness I don't recall a reference to
that particular month but I believe the question was
phrased in terms of the period in which we are
interested.

15

16

A. But there are six or seven
months that we are interested in .

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Q. I appreciate that, Doctor, I
appreciate that, but those are simply the figures you
gave at that time?

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A. Yes.

Q. Do you have more precise figures
with respect to claimed values for the individual
months?

A. Well, I could present a sheet



B.6

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of claimed values if you so wish at some stage a
little later on after I have an opportunity to find it.

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THE COMMISSIONER: Well, I have some
reservations about it. Because once again as I say
this is not - and I don't like to cut people off in
cross-examination, but all of this should have been
gone into before, we should not be having it now,
that's all. Where did you get the claimed values,
did you get it from some evidence?

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MR. BROWN: From Volume 6, page 822.

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THE COMMISSIONER: From 8 ---

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MR. BROWN: Page 822, I believe at
that page there is a reference to the Ortho Company.

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THE WITNESS: I believe when that
information was given over it was with respect to
giving an appreciation or an approximation as to the
amount of analytical error in the assay, not in
relation to March 16th, 1981 specifically.

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MR. BROWN: Q Well, I simply wanted
to discuss with you, Doctor, the possibility of the
range of analytical error in the assay.

21

A. Oh, okay.

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Q. Simply no more than that, in
the realm of possibility, I am not seeking a definite
conclusion with respect to each sample.



B.7

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THE COMMISSIONER: But the control values are all different, are they not, each day?

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THE WITNESS: Yes.

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THE COMMISSIONER: They are all different.

6

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MR. BROWN: Well, I agree Mr. Commissioner that control values do fluctuate from day to day. I was simply going to ask the doctor the significance of that fluctuation.

9

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THE COMMISSIONER: All right.

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MR. BROWN: Q. If we may turn then to the Control B which gave a reading of 2.5 on March 16th. If you would assume with me that the claimed value for Control B was 2.0, would I be correct in saying then that with a claimed value of 2.0 plotted at 2.5 on that particular day, assuming a claimed value of 2.0?

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A. I am sorry?

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Q. Assuming that in fact in Control B there was as the manufacturer claimed only 2.0 nanograms per millilitre of digoxin; on March 16th when you ran the assay the level which you plotted for Control B was not 2.0, it was 2.5, is that correct?

23

24

25

A. Yes, we obtained a value of 2.5



B.8

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for Control B on March the 16th, that is correct.

3

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Q. And assuming that Control B contained the amount of digoxin the manufacturer claimed it did have?

5

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A. Well, you are assuming that.

7

Q. I am simply asking you to assume I am putting it no higher than that, Doctor.

8

9

A. Okay.

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Q. Assuming that it did, one could then say that on that particular day a control sample which was claimed to have a 2.0 nanograms of digoxin plotted at 2.5 nanograms of digoxin, is that a fair possibility?

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A. Yes, if your assumption
is correct.

Q. If the assumption is
correct. And if the assumption is correct, that
would then indicate that in the area of the curve
where you get readings of 2.5, there may be some
irregularity in the sense that a known sample with
2.0 plotted at 2.5 and that irregularity may well
be within your accepted realm of deviation. Would
that be fair to say?

A. Yes.

Q. Yes. And on that day
you may well be satisfied with the shape of the
curve, notwithstanding that discrepancy?

A. Yes.

Q. Would that be fair?

A. That is fair.

Q. But would it also be
fair to say that there would be a possibility that
any sample that you assayed on that day, which gave
a reading which plotted at 2.5, may possibly only
contain 2.0 nanograms of digoxin. Would that be a
possibility?

A. It may possibly, yes.

Q. And that is because it
appears that there is a discrepancy between the



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control value and the plotted value for Control B?

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A. Yes.

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Are you eventually going to get to the idea that Tube 15 is 2.6 times 10 and that value was ultimately reported and therefore if the dilution is times 10, you are trying to bring up the issue that it is conceivable that that result might have been 20 as opposed to 26? Is this the point you are getting to?

10

11

Q. Well, that will save us a lot of questions, Dr. Ellis, yes.

12

A. Okay.

13

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Q. That is precisely the question that I'm getting to.

15

16

A. Thank you.

Q. We will then turn to Item 15.

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A. Fine. Okay.
Q. And in that particular case you ran the patient sample and you did obtain a reading of 2.6.

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A. Yes.

Q. On the graph.

A. All right.

Q. Would it be possible,



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since that reading is in the neighbourhood of 2.5, would it be possible that the 2.6 in fact is a lower value closer to 2.0? Would that be a possibility?

A. That would be a possibility, yes.

Q. And if it is a possibility then that by reason, and this would be by reason of the discrepancy shown between the claimed value for Control B and the plotted value for Control B, would that be correct?

A. Not for those reasons but it would be a possibility. There is always random error in any assay and any individual number has to be regarded, you know, in the light of an individual number.

Q. Yes.

A. Just as Tube 2, Control B has to be regarded as a pair of assay tubes, but in fact you will see that 12, 13, 14, 15 are not just a pair of assay tubes like Tube 2, but they are two assay tubes assayed neat and unable to obtain a result; two assay tubes analyzed times 5 giving a result two assay tubes further, Item 14 assayed times 5, two assay tubes analyzed under the same conditions as Control B, Item 2, so that the level of



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confidence that you have in the ultimate results, the 25.5 or the 26 that was reported is greater in this particular batch than it is for Control B in that individual batch. But, however, the points that you are making are taken.

Q. Well, I take it, Doctor, that with respect to Items 13 and 14 which you diluted on a times 5 basis, the readings which you were able to plot on the graph were at the upper end, at 4.8 and at 5.1?

A. That's right.

Q. Would I be correct in saying that because the readings were plotted at the upper end of the scale you thought it prudent to conduct a further dilution to get a reading which would plot in a more central portion of the graph? Would that be a fair statement?

A. We did Tube 15 alongside Tube 14 without knowing what the answer to Tube 14 was.

Q. Okay.

A. So, when I viewed these results at or around this time and decided what results should be taken, I took an average of these, however many tubes there are, six tubes.



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Q. Well, that is certainly fair enough. But with respect to Item 15 you would then agree with me that there is a possibility that the 2.6 plot may not necessarily represent 2.6 nanograms per millilitre of digoxin but may possibly represent a lesser value of digoxin closer to 2.2 nanograms of digoxin?

A. Yes, or possibly even a greater amount of digoxin.

Q. Well, if I can refer you to Item No. 26, which is the Control C and the reading which you plotted for that day was 3.0.

A. Yes.

Q. And assuming that the claimed value for Control C is in fact 2.8 nanograms per millilitre would it be fair to say that the curve at that portion of the graph also indicates a value slightly higher than the amount claimed for the sample?

A. Yes. Well, the amount claimed -- the amount normally obtained?

Q. Yes, in the circumstance where the manufacturer claims the reading, what you will get will be 2.8 and in fact you have plotted 3.0. There is a discrepancy of, between the plotted value



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and the claimed value. Is that fair?

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A. Well, without knowing exactly what the claimed value was, the 3.0 value was 2.9 on the subsequent date and on the previous day had been 2.8. So, I take your point that it appears to be very slightly higher than it had customarily been around this time.

Q. Well, would it be fair to say then that the value you would get in the portion of the curve around 3.0 may well be, may possibly be slightly elevated over the amount which is actually contained in a particular sample tube?

A. It may possibly, yes.

Q. It may possibly be.

THE COMMISSIONER: Why can you not trust the manufacturer's figure? Why do you make the assay on the control?

THE WITNESS: Because he doesn't actually supply us with an absolutely precise figure. He provides us with a range of figures, depending upon which assay is being used. You will get a different answer depending upon which assay kit is being used. This is the information that he provides us with.

THE COMMISSIONER: So, you would



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have to every day check the control, I take it,
do you?

THE WITNESS: Every day we have
to see how the control shapes up with our ideas as
to what it should be. But the manufacturer doesn't
say that the value should be 2.00 plus or minus zero.
He doesn't give us that degree of precision.

MR. BROWN: Q. Well, you have
fairly said to me, and you have qualified it, that
Item No. 15 may be closer to 2.0 than to 2.6 and
possibly done on dilution, the value may be closer
to 20 than to 26, subject to all the other qualifica-
tions you have put on the Pacsai assays for that
day.

A. Yes, and subject to the
other results that had been obtained on that same
autopsy sample.

Q. Oh, yes. If we could
return then to page 27 at Tab 45. It was my under-
standing that you re-assayed those same samples
three days later on March 19th, is that correct?

A. Yes. These were assayed.

Q. That's correct. And you
obtained two readings, 25 and 24.

A. Yes. Controls B and also



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Controls C were closer to the values that you were accepting a moment or two ago as well you will notice.

Q. Yes, I agree that they are. Control B instead of being 2.5 on this day was 2.3. But assuming the claimed value of the manufacturer as 2.0, the plotted value would still be higher on that day than the claimed value for that control by the manufacturer, wouldn't it?

A. Under that assumption.

Q. Under that assumption. And assuming that that assumption is correct, then a reading which you plot in the 2.3 neighbourhood may indeed be an elevated reading in the sense that the sample may in fact contain slightly less digoxin than is plotted on the curve. Is that a fair possibility?

A. Yes.

Q. So, turning then to Item 4, which was one of the Pacsai samples that you ran, you obtained a reading of 2.5, is that correct?

A. Yes.

Q. So, there would be a possibility, since 2.5 is in the neighbourhood of the 2.3 plot, that the 2.5 is slightly elevated and in fact the amount of digoxin contained in that



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sample may have been less than 2.5. Is that a possibility?

A. Yes.

Q. So that on a dilution times 10 it is possible that the reading may not have been 25 but may have been of a value less than 25?

A. Yes, or more than 25.



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Q And similarly Control A on that particular day gave a reading of 1.2; is that correct?

A That is what it says, yes.

Q And the claimed value I am asking you to assume that the manufacturer gave for Control A was 1.0?

A Yes.

Q And accepting that, if you turn to Item No. 5 on the Pacsai sample, the result which you obtained for the Pacsai sample was a plotted reading of 1.2; is that correct?

A Yes.

Q And would it then be a fair possibility that the plotted reading of 1.2 may be slightly elevated and in fact that sample only contained an amount of digoxin of 1.0?

A Yes, or it might be higher.

Q And that on dilution if it did contain a lower amount closer to 1.0, on a times 20 dilution the answer may be closer to 20 than to 24; is that a possibility?

A Yes, or even to 30 than 24.

MR. BROWN: Thank you, Doctor. Those are my questions.

THE COMMISSIONER: Mr. Dodds?



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MR. DODDS: No.

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THE COMMISSIONER: Mr. Hunt?

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CROSS-EXAMINATION BY MR. HUNT:

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Q. Dr. Ellis, my name is Hunt and we represent the Attorney-General and the Coroners.

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Sir, you indicated for us last week that at some time during the week of the 12th someone whom you can't specifically recall came to you and asked you to do some tissue testing. Do you recall how long it was after the death of Kevin Pacsai that that occurred? He died on the 12th of March.

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A. You are referring to the 12th of March, are you?

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Q. Yes.

A. The week following that? No, I can't, but it would have had to have been before the analysis took place.

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Q. Which was the 20th of March? Do I have that right?

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A. Whatever it says on the bit of paper that --

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Q. All right. In your digoxin kit book it indicates that you first ran the analysis on the various samples that you got from Virology on March 20th?



D.3

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A. Yes.

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Q. Which was a Friday?

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A. Okay.

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Q. So it is somewhere between the 12th and the 20th when you were first approached with this request?

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A. Yes.

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Q. And I think you indicated as well that it was not you that chose the various samples to analyze?

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A. Yes. I don't remember specifically this particular - the exact contents of this meeting, you know, so exactly who chose what I can't absolutely remember. I think Dr. Cutz indicated, didn't he in testimony, that two names had been mentioned by him or something?

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Q. Well, I am just trying to see if we can get any closer at all to the question of who it was --

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A. Yes.

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Q. -- who asked you to run these tests?

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A. Well, it's difficult because I think I mentioned the possibility - I tried to remember it when I was previously here. I thought at that



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particular time it was Dr. Freedom of Cardiology. I spoke to him after that time and asked him whether it was him and he said it wasn't, and I can't find anybody who remembers speaking to me even though I have asked them about it. So I can't specifically tell you who.

Q. I see. Did you ask Dr. Fowler whether it could have been him that asked you to run the test?

A. I think I have asked Dr. Fowler, Dr. Costigan, Dr. Mancer. I don't remember asking Dr. Cutz, but I kind of went round afterwards and tried to find out if anybody remembered this. But the conversation, if I recall correctly, took place in my lab but I can't remember who was asking me.

Q. Well, we have heard that Dr. Fowler during that week was asked by Dr. Carver to carry out some inquiries into the question of digoxin dosages.

A. Yes.

Q. And he has indicated that he did speak to a number of people with respect to Kevin Pacsai.

A. Yes.

Q. And my query to you is whether or not Dr. Fowler had indicated he had any recollection



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of speaking to you about analyzing tissues of other
children?

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A. No. As I say, I don't remember
specifically who asked me.

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Q All right. Well, in any event
in addition to Kevin Pacsai you analyzed tissues
from a baby named Whitehead?

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A. Yes.

9

Q And Jordan Hines?

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A. Yes.

11

Q We know that Jordan Hines was
not on digoxin.

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A. Yes.

14

Q And I have looked through the
digoxin book and I can't see any reference to Baby
Whitehead. Now I may be wrong there, but assuming
that he also was not on digoxin or he would have
showed up there --

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A. Yes.

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Q Would that be normal to have
two control samples in a situation like that from
children who weren't on digoxin?

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A. I can't remember the exact
circumstances under which I obtained those tissue
samples, but what you say is quite likely that we were

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D.6

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2 interested in the Pacsai case - this followed the
3 Pacsai case - and ultimately I went to Virology and I
4 obtained some tissue samples, and I think I have
5 indicated previously last week that if one was doing
6 some kind of experiment, even a terribly preliminary
7 experiment, one would be interested in tissues of
8 patients who had been on digoxin and patients who had
9 not been on digoxin and any combination or permutation
10 of that particular decision.

11 Q What I am trying to get at is
12 the question of whether or not those samples (that is
13 Whitehead and Hines) were picked by someone because
14 they represented appropriate control samples or whether
15 they were picked because there was some question about
16 Whitehead and Hines, and for that reason you were
17 asked to analyze those samples because I think you
18 indicated you had a vague recollection that at the
19 time of this discussion there was possibly some
20 mention of concern about other children?

21 A Yes.

22 Q Who had died as well. So would
23 it not, if you were looking for pure control samples,
24 have been better to have had perhaps one that was not,
25 a child who was not on digoxin and a child that was?

A It would, yes. Yes, if one was



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only going to do two I think that would be what one would try to do, and also one would try to get samples of the same age and sex and clinical condition if possible.

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Q All right. So does the fact that you were given names as opposed to carrying out some inquiry of your own with respect to control samples, does that suggest that perhaps somebody chose these because they were interested in the results of your analysis on these particular children?

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A It is one possibility, yes.

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Q Would that seem more likely in the circumstances than those having been selected purely as controls?

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A Yes, but I can't tell you who Whitehead is. As far as I know he was just a sample, or she, was just a sample in Virology. I just cannot tell you specifically, I don't know.

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Q All right. Now the 20th of March was a Friday and I am correct you began your testing on that day? I am just going by the note.

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A Sure.

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Q On page 171 in Exhibit 210.

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A I think the analysis was performed on that day, and I cannot tell you whether the



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preparation of the materials took place on that particular day or just before it. And I cannot tell you exactly when I picked the samples up from Virology.

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Q. In the note on page 171 it says that these, referring to the samples --

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THE COMMISSIONER: What is that exhibit?

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MR. HUNT: It is Exhibit 210, Mr. Commissioner, page 171. Three or four pages from the back of the exhibit.

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Q. I will just read you the one pertinent sentence.

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A. Yes. Sure.

Q. It says "These", referring to the samples:

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"These had originally been assayed by Mladen and myself on 20 March, page 28 in the regular work book."

And then at page 28 of Exhibit 45 of the preliminary hearing there is reference to the three children, Hines, Whitehead and Pacsai.

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I don't think it is really critical to my question, sir, when you picked them up from Virology but it would appear that on the 20th you ran



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the assays for the first time?

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A. Yes.

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Q. Now would you know whether or
not you would have the results back on the 20th?

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A. The results back?

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Q. Yes.

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A. Whether I personally had the
results back?

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Q. Or whether they would be
available that day or the next day?

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A. These were analyzed as part of
a batch of 24 samples along with patient samples, so
it is fair to assume that if the patient sample
results were produced on that day that these results
would have been produced on that day and they would
have been available for me to look at on that day.

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Q. All right.

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A. So I could well have seen these
results on that Friday.

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Q. All right.

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Now also on March 20th, which was
the Friday, I believe Dr. Tepperman came to your
office late in the day to pick up the chart for
Baby Estrella?

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A. Yes.



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Q. And were you aware at that time that he was the coroner responsible for the Pacsai case?

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A. At that particular time - well, I was aware that he had been informed of the Pacsai case because I think Dr. Cutz had contacted him earlier in the week. Isn't that the case in relation to that case?

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Q. Yes, that is correct. As a matter of fact he contacted - or the evidence has been he was notified of Kevin Pacsai's death on the 12th of March.

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A. Oh, yes.
Q. So were you aware as of that day that Pacsai was a coroner's case?

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A. On the?

Q. By the Friday?

A. By Friday the 20th?

Q. Yes.

A. Yes, I was.

Q. Now when Dr. Tepperman was there I take it you had some conversation with him at that time?

A. Yes.

Q. Was that with respect to just



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Estrella or did you discuss Pacsai as well?

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A. We discussed - it was a very brief discussion but we did discuss both those two cases in a very brief way, yes.

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Q. All right. Do you recall mentioning to him in respect of Kevin Pacsai at that time about the antemortem sample where the level was greater than 10 nanograms per millilitre?

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A. Not specifically at that time.

Q. All right. Did you on the 20th advise him that you had begun testing the tissues of Kevin Pacsai?

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A. No.

Q. Did you - I take it then you also wouldn't have mentioned you tested the tissues of Jordan Hines or of Baby Whitehead?

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Q. Was there any reason why you didn't advise him at that point in time about the testing?

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A. Well, because of the testing, of those particular samples, was not really relevant as far as I was concerned at that particular time because basically our conversation, as I think I indicated previously, in relation to these two instances



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was that as far as I was concerned on that Friday we
might possibly be dealing with a medication error --

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Q. Yes.

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A. -- you know, and so in that he
was a coroner.

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Q. Wouldn't that be relevant even in
respect of Kevin Pacsai given that that was a
coroner's case as of Friday?

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A. I just didn't think about that
particular angle that you are bringing up now.

11

Q. All right. That is fair enough.

12

With respect to Jordan Hines you
found evidence of digoxin in the tissue?

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A. Do you mean on the Friday the
20th?

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Q. Well, after you ran the assay
the first time?

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A. No. I think that is not correct.

18

Q. All right.

19

A. I think on Friday the 20th, on
page 28 of the book --

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Q. Yes.

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A. -- it looks as though it is
under .2 for everything, doesn't it?

23

Q. All right, yes.

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A. It looks as though there is
nothing there.

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Q. Yes.

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A. But on the other hand, you know,
these analyses --

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MR. HUNT: Sorry, Mr. Commissioner. It
is page 28 of Exhibit 45.

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THE COMMISSIONER: Oh, yes. I beg
your pardon. Page 20?

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MR. HUNT: Page 28 of Exhibit 45.

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THE COMMISSIONER: Yes. All right.

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MR. HUNT: Q. You are quite right, it
would appear to be under 2 so you were about to say
when the first time that you found evidence of digoxin
in tissues of Jordan Hines was.

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A. No. I think you said that.

17

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Q. Well, I suggested it was the
Friday and you quite properly pointed out that it
would appear that wasn't the case on Friday.

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A. It would appear either there
is nothing there or possibly the assay needed more
work on it.

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Q. All right.

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A. Now I put that in retrospect.

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Q. So then would it be on March 25th
as appears in the digoxin kit book at page 171?

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A. Yes.

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Q. So that appeared to be the first day on which you found evidence of digoxin in the tissues of Jordan Hines?

A. That would be the first day that some kind of reading that might suggest that was obtained.

Q. All right.

A. But it has to be taken into account that we had obtained these other previous results on the Friday.

Q. Now to summarize it insofar as Dr. Tepperman is concerned, when he left your office on Friday, March the 20th, as far as you are aware he was not aware of the fact that you had done any testing of any tissues on Kevin Pacsai, Jordan Hines, or Baby Whitehead?

A. That is correct, yes, I don't think he would have any reason to believe that.

Q. And even after the 25th was concerned, March 25th, you didn't have any communication with him with respect to your testing or the findings?

A. My testing or the findings? I didn't have any communication with him?

Q. Yes.



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A. After the 20---?

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Q. The 25th.

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A. The 25th of March? How far
into the future do you then go, do you go that week
or ---

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Q. Do you recall ever talking to
him about your testing and telling him the results
that you got on the 20th and on the 25th with respect
to Pacsai or Jordan Hines?

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A. Do I recall ever discussing
these results with Dr. Tepperman?

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Q. Yes.

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A. Yes, almost a year.

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MR. HUNT: Thank you. Those are all
the questions I have.

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THE COMMISSIONER: Thank you.
Mr. Percival.

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CROSS-EXAMINATION BY MR. PERCIVAL:

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Q. Dr. Ellis, I want to take you
one step further than Mr. Hunt has with reference to
what developed over the weekend of March 21st and
22nd.



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Mr. Commissioner, may I preface this by saying that my friend Miss Cronk brought this up in relation to the events of March 24th and I feel I must deal with that aspect of it.

You have indicated already in your evidence, Dr. Ellis, that you were away on the weekend of March 21st-22nd.

A. I was ---

Q. Away, in other words not on duty at the Hospital.

A. I was not on duty at the Hospital.

Q. Yes, all right. Were you aware of what was transpiring at the Hospital during that weekend, quite apart from whether you were there?

A. Not until the Monday morning.

Q. And then there were two meetings on Monday, March 23rd and Tuesday, March 24th involving a number of physicians and the police, did you attend any of those meetings? I am talking about formal meetings.

A. In the Hospital you mean?

Q. Yes.

A. Did I attend?

Q. Yes.



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A. No, but I believe my boss
Dr. Hill attended.

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Q. I understand that. Were you
then, after those meetings, advised by Dr. Hill what
had transpired, generally speaking?

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Q. And do I take it that on
March 23rd and March 24th, being the Monday and
Tuesday, that both from what Dr. Hill had told you
and from the digoxin book and other sources, that
high digoxin levels had been found both ante mortem
and post mortem in the blood or serum of Baby Cook?

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A. Yes.
Q. And you were aware then I
gather on March 23rd and 24th also that Baby Cook,
at least so far as you are aware, had never been
prescribed digoxin in the hospital?

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A. I was aware of that fact at
that time.

Q. And then you told us on March
24th, which is the Tuesday, at about 3:45 p.m., and
this is at page 992 of the transcript, Mr. Commissioner,
you told us that Sergeant Barbour attended at your
office and gave you a number of different tissue
samples?



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A. Ahem.

Q. Is that correct?

A. That is my recollection, did he ---

Q. I understand, and I believe in your evidence at page 994 you indicated that he expressed some interest in relation to three tissue samples involving Baby Cook and that ---

A. Tissue or fluid samples?

Q. Whatever it was, three samples in any event.

A. Three samples, yes.

Q. And while you had been inclined to think about doing them the following day, he indicated to you that there was some degree of urgency involving those three samples?

A. Yes.

Q. Involving Baby Cook?

A. That was my understanding.

Q. I understand, and as a consequence of that you stayed on that evening and did the necessary sampling that you have indicated already in your evidence?

A. Yes.

Q. And in addition to doing the



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preliminary samples involving the gastric sample,
the bowel sample and the chest sample, you also
did a repeat serum sample with respect to Baby Cook
that early evening?

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A. I think that is correct.

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Q. I think that is in your
evidence in any event thus far, Dr. Ellis.

9

A. Okay.

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Q. Do I take it then when those
results were known to you involving the bowel and the
gastric juices and the chest, when they were analyzed,
when the presence of digoxin was discovered by you
that was not surprising, the presence of digoxin in
those samples was not surprising because you were
already aware of the fact that he had digoxin in the
blood?

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A. Yes.

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Q. And any high levels in the
bowel or the gastric juices or the chest were not
unexpected I suggest, Dr. Ellis, in view of the
previous results, the high levels in the blood, is
that correct?

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A. Yes.

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Q. Now, I want to deal with the
phone call then that you made following those -



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having done those tests and reaching those provisional results. Do I take it that you called Sergeant Press that evening?

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A. I think I did, yes.

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Q. What I want to deal with, if I may, is as to what you communicated to Sergeant Press that evening.

9

A. Ahem.

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Q. Do I take it that you merely told him that you had done the three analyses of the gastric, the bowel and the chest and that there was digoxin in them?

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A. I think on that occasion I indicated that the results, the results taken, simply the results I had obtained suggested there were very high amounts particularly in the bowel.

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Q. Do you recall saying anything else at that particular point, and I want you to be specific if you can in your recollection?

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A. Yes. I think I basically in relation to Miss Cronk's questions I indicated that I had put certain qualifiers on those results because they were very preliminary.

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Q. I understand that. What I want to know is what those qualifiers were that you can



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recall expressing to Sergeant Press. Do I take it from your evidence that one of the qualifiers were that - did you tell him that this was the first time you had ever done digoxin assays involving bowel content and body fluids?

7

A. I may well have told him that.

8

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11

Q. What do you recall? You see, I can suggest many things you might have said but I want to know what you can recall as to the concern or reservations that you expressed to Sergeant Press. Did you express that to him, or do you recall?

12

A. That specific ---

13

14

15

Q. Yes, that this was the first time you had ever done them so whether they were accurate or inaccurate you couldn't tell at that point?

16

17

A. I can't recall whether that specifically came up, I put it ---

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19

20

Q. Well, did you tell him on that occasion that quite apart from the results being high that you wanted to do further tests or assays?

21

A. Yes.

22

Q. You recall saying that?

23

A. I recall communicating that idea to him.

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Q. And did you express to him that you were concerned whether or not the results were accurate or inaccurate?

A. Yes.

Q. Any other reservations or concerns that you expressed to him at that time?

A. Well, I was particularly concerned, and I may have, on that occasion referred to the fact that this, the high results that had been obtained were on bowel contents and I may have discussed the idea of proteolytic enzymes and digestion and its possible interfering effects on the assay.

Q. All right. Do I take it what you were telling him is that there may have been things that occurred in the stomach that might cause you to doubt the accuracy?

A. Not in the stomach quite so much as in the assay tube that I was using.

Q. Anything more than that that you can recall your doubts or concerns?

A. Not right now.

Q. Now, on page 1032 of your evidence on Thursday, Dr. Ellis, you talked in terms rather generally in response to a question of



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Miss Cronk's about the method of administration of digoxin and whether it should be given orally or intravenous. Do you remember giving that evidence on Thursday?

A. Yes.

Q. Do I take it, Dr. Ellis, that that was something that you first considered many months after you had done those first analysis involving the bowel, the gastric juices and the chest tissues? I say that to you because on an earlier occasion, Dr. Ellis, you gave evidence in the preliminary hearing, in Volume 12 of the preliminary hearing, Mr. Commissioner, on February 8th of 1982 at page 46, that the results that you took in relation to the bowel contents only took on certain significance when you read a particular paper in the Journal of Forensic Science, do you remember giving that evidence?

A. I remember discussing that paper at the preliminary hearing, yes.

Q. Do you recall saying, and I quote this to you at the top of the page:

"A. I have never had any experience before this particular date of any analysis on bowel contents. These



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"results only took on a certain significance when I came across a paper. This paper was in the Journal of Forensic Science, Volume 20, 1975 and the page was 340 to 347."

A. Ahem.

Q. Now, do I take it that a number of months after March of 1981 and prior to February 8th, 1982, you came across this particular paper?

A. I came across that particular paper, yes.

Q. Yes, but when is what I am asking. I gather you didn't have the paper in your hands when you called Sergeant Press that night?

A. Oh, no.

Q. Do I take it then it was many months later that you started to attach certain significance to the results of the bowel contents involving Justin Cook?

A. Oh, no, I attached on that night, the 24th of March, a significance to the fact that as far as I could tell there appeared to be very large amounts of digoxin in the gut.

Q. I understand that. What I am



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talking about is did you really address your mind
to the method of administration that night?

A. Yes.

Q. Do you recall talking of that
to Sergeant Press?

A. I recall either then or within
the next few days this discussion of the method
of administration coming up in conversations between
myself and Sergeant Barbour.

Q. Well, in particular, had you,
prior to that evening with Sergeant Press, had you
discussed with Dr. Hill what seemed to be the
complete and total unanimity of expression that there
had to be an intravenous injection involving the
digoxin, at these meetings on March 23rd and March
24th?

A. No, I haven't discussed that
unanimity that took place.

Q. You are aware of the unanimity?

A. Only in respect of the conversa-
tion that took place between myself and Sergeant Press
on a very much later occasion in 1982.

Q. Do I take it then that prior
to that, the evening of March 24th, in your discussions
with Dr. Hill he never talked to you about the method



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of administration that was then being considered?

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A. I have no recollection of him communicating specifically that information to me.

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However, in relation to the large number of samples that were brought to my lab by Mr. Barbour, only

7

three of them were of interest to him on that occasion.

8

Q. I understand that.

9

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A. And looking at this - it is a long time since, okay. It was just my understanding that they were of particular significance because bowel contents were what were of interest to the police at that particular time.

11

12

13

Q. Do I take it what you talked to Sergeant Press about was the results were high, that they were preliminary?

14

15

A. Very high.

16

17

Q. I have some concerns about them and I will get back to you.

18

19

A. Yes. I think this could well have been the general conversation, yes.

20

21

Q. You see, general conversation may assist you, but I want to know what you can recall. Do you have a specific recall of that telephone conversation?

22

23

A. A specific recall, no.

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MR. PERCIVAL: Thank you. No
further questions.

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THE COMMISSIONER: Thank you.

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Yes, Mr. Knazan. I guess, Miss Kitely,
you have been supplanted, you were supplanted on
Thursday.

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MS. KITELY: Thank you very much, sir.

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THE COMMISSIONER: Yes, Mr. Knazan.

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THE COMMISSIONER: Mr. Knazan?

Miss Chown, your views are exactly the same as they were a few minutes ago, I take it?

MS. CHOWN: Yes.

THE COMMISSIONER: Yes, all right.

CROSS-EXAMINATION BY MR. KNAZAN:

Q. Doctor, I represent Mrs. Christie, who is a Registered Nursing Assistant at the Hospital.

Doctor, whether you use 4.7 or 5, am I correct that a report, a figure of higher than 5 should never find its way onto the final report which goes up to the requesting ward?

A. Should never or did not in many cases?

Q. Well, it should not. That is, above 5 you do not consider accurate?

A. But you have seen results of 72 and you have seen results of...

Q. No, I'm sorry, before dilution.

THE COMMISSIONER: I think he means before the first assay.

MR. KNAZAN: Q. Before dilution.



1
F2 2 A. Oh, okay. In other
3 words, if you just do it singly neat and it comes
4 over 5 do you report the answer that you get?
5 Q. That's correct.
6 A. By the computer.
7 Q. Yes.
8 A. No you don't.
9 Q. Or if you were to dilute
10 it and the result came out to about 5, you wouldn't
11 report that result multiplied by the dilution?
12 A. No, not on that occasion.
13 You may give some indication that it is greater than
14 a particular value, depending on the dilution.
15 Q. Okay. Well, it is not
16 a large amount but if you turn to the Pacsai reading,
17 Exhibit 32B, Tab 46, page 24 -- it is Tab 45, I'm
18 sorry. Do you have that, Doctor?
19 A. Yes.
20 Q. Assuming whoever was
21 doing this was using 5 at the time and not 4.7, if
22 you look at No. 14 you will see that they got a
23 reading of 5.1 and they multiplied it by 5 to get
24 a reading of 25.5.
25 A. Yes.
Q. Would you agree that that



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was incorrect, that it should have been no higher
than 25?

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A. It is hard to say without
having the specific curve in front of me. You have
to look at that result alongside all the others
around it, you see.

5

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7

8

Q. Well, you do, because the
25.5 is a measure derived from the three readings of
24, 25.5 and 26, right?

9

10

A. Yes.

11

12

Q. What is that, is that
the mode or the mean?

13

A. Is that the average or
what, I don't know, it doesn't even work out.

14

15

Q. Well, it is neither, it
is closer to 26 than 25. It is the middle figure.

16

A. Okay.

17

18

Q. Okay. But looking at
No. 14 in isolation, if you are using 5 or 4.7,
a reading of 5 should not be reported, that's the
purpose of the further dilution?

19

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A. Yes.

21

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Q. A reading of greater than
5 should not be reported?

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A. You are placing that

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emphasis on it now. I would say that if a reading of 9 or a reading of 8 had been produced by the computer, that would be totally disregarded for the purpose of calculation of an accurate result, the result is as accurate as we could obtain it.

Q. So, you consider this result is accurate given though the general cut-off is 5?

A. I considered the result of 26 that was ultimately reported to be the most reliable result that we could have produced on that day under the circumstances that we did it.

Q. I understand that, but I am just trying to arrive at how you found the 26 because the 26 appears to be 25.5 rounded off and 25.5 appears to be the middle figure of three tests. Is that correct?

A. Well, what's the problem exactly? We reported 26, did we? Did we report 26?

Q. It's the figure of 26 that gets into the final autopsy report.

A. Isn't that Item 15 times 10, 2.6 times 10, and isn't that approximately the value that we are getting for the other two?

Q. So, that is where the



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reading comes from?

A. Yes.

Q. I see. Thank you.

Now, Doctor, you testified to Miss Cronk the main purpose of doing these assays was to advise the clinicians so that they could be aware of the proper dose to administer to the child, is that correct?

A. Yes.

Q. And all of the technologists in your lab would be aware of that?

A. Yes.

Q. And you also testified that the clerical staff sometimes enters a figure from the book to the computer?

A. Yes.

Q. And they would also be aware of the use to which these readings were going to be put?

A. They may well not.

Q. Well, are they aware of the importance of reporting a correct figure?

A. Other than they are aware of the importance of reporting a correct figure but may not be aware of its clinical significance.

Q. No, I understand that,



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but they are aware that the clinicians are
depending on these figures being correct?

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A. Oh, yes.

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Q. In order to make the
determinations which affect the child's health?

6

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A. Yes.

8

9

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Q. So, I take it everyone,
yourself, your technicians and your clerical staff,
would take pains to make sure the decimal points
were correctly reported?

11

12

A. We would take pains to
do that, yes.

13

14

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Q. So, in the five years,
say, from 1976 when you began to 1981, do you ever
recall a clinician coming back to you and questioning
a reading and you having to say, you're right, we
put the decimal in the wrong place?

17

18

A. Do I have a specific
recall of that on a particular occasion?

19

20

Q. Yes, do you ever recall
that happening?

21

22

A. Errors have been made
in the transcription of results in the general sense.

23

24

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Q. Was that a frequent
occurrence or a rare occurrence?



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A. A relatively infrequent

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occurrence.

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Q. Now, you testified about

5

your control tests for the concern about EDTA.

6

A. Yes.

7

Q. Is that the same concern

8

that Dr. Costigan referred to when he testified about

9

his concern about a CBC tube, a complete blood

10

count tube, is that the problem?

11

A. I don't know exactly

what he said on that occasion.

12

Q. That's fine.

13

A. But it could well be, yes.

14

Q. So that the concern

about taking blood in a complete blood count was

15

thesame as the concern about the EDTA?

16

A. It was not our usual

17

practice to take blood for digoxin assays in a CBC

18

tube.

19

Q. Now, you stated that you

20

reviewed the results of the Pacsai readings even

21

though you did not do them yourself, you told that

to Miss Cronk.

22

A. Yes.

23

Q. What did that review

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consist of? This is at Volume 49, page 73. On Monday when the assays had been completed, did you then review the various results in an effort to satisfy yourself one way or another as to whether the assays had been performed correctly?

A. Wasn't my reply at that time that either on that occasion or within a few days of that I did in fact review these results?

Q. Yes, the answer is here. I'm asking, what did the review consist of.

A. What did the review consist of?

Q. Yes.

A. Well, it consisted at least of looking down the results of March 16, 1981.

Q. Okay.

A. I have no specific recall as to whether I went back to the original printouts or whether I recounted the tubes. I suspect I probably didn't. I guess part of the process was also to repeat that sample again later in the week, wasn't it? Didn't the review process involve, on the 19th of March, a re-analysis of that autopsy sample? So, certainly that must have been discussed. Items 4 and 5 on the 19th of March, that particular



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F9 2 sample was re-analyzed. My staff would normally
3 have done that.

4 Q. So, the review consisted
5 of actually redoing the sample?

6 A. That was one aspect.

7 Q. Now, turning to that,
8 which is page 27 of Tab 45, Exhibit 32B. Why,
9 when there was a reading of under 5 or under 4.7
10 on the times 10 dilution was it necessary to do a
11 times 20 dilution? Perhaps you mentioned this and
I missed it.

12 A. This was which page?

13 Q. Page 27, the repeat of
14 the autopsy sample that you just referred to on the
15 19th of March, Nos. 4 and 5 at the top of the page.

16 A. Because we got a result
17 on March 16th on a times 10 dilution?

18 Q. Yes.

19 A. Your question is what?

20 Q. My question is, on March
21 19th when you did the first times 10 dilution --

22 A. Yes.

23 Q. -- you got a result well
24 within the reliable range, if I could call it that.
25 It was nowhere near 4.7 or 5.



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A. On March 19th?

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Q. March 19th, No. 4, page

4

27.

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A. All right.

6

Q. Why was it then necessary

to dilute times 20?

7

A. But this took place in

8

the same batch.

9

Q. I see.

10

A. So, a decision had been

11

taken on March 19th prior to Result No. 4 being

12

obtained to dilute it times 10 and times 20. We

13

were, if you like, being a little bit more thorough.

14

Q. So, that was done

simultaneously?

15

A. Yes.

16

And the other aspect is,

17

this question of dilution along a standard curve

18

that I brought up last week, if there is digoxin

19

material it should dilute out without certain

20

error limits.

21

Q. You also testified that

22

the only concern about the first Pacsai reading of

23

greater than 10 was that there was only one tube and

24

you went on to explain that in some detail. Do you

25



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recall that testimony?

3

A. My only concern was that

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there was only one tube.

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Q. Only one tube, yes.

6

A. But wasn't there a CBC

7

tube as well? I thought I had mentioned that. I

8

mean, wasn't this (a) an EDTA sample, (b) not very
much left and (c) only analyzed in one or two tubes?

9

Q. Well, page 856 of

10

Thursday's testimony, line 8, Miss Cronk asked you:

11

"Q. All right. And do I have

12

it then correctly that your con-

13

cern today and your only concern

14

with respect to this level and its

15

validity is the fact that in the

16

aggregate there were only two tubes
available?"

17

"A. Yes."

18

Now, it's all right, I accept that

19

you may have been concerned about the source of the

20

sample but you satisfied yourself about the EDTA.

21

I just want to understand why there is a concern

22

about only one tube. Is that not related to the

23

complexity of the test of the assay, if I may put it
that way?

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A. Well, it is our normal practice to analyze two tubes and therefore if we don't perform the assay in our usual way we can put less emphasis on the individual tubes.

Q. Yes, but generally the requirement for repeat experiments would be related in some way to the complexity of the experiment?

A. Yes, you could say that.

Q. If I sent you a sample and said I don't have the measuring tube in my lab, could you tell me how many millilitres there are in this bottle, you would only have to run that once, right, it is a very simple experiment but because of the complexity of the assay you have decided that you require two readings and that's why you were concerned about the validity in that case?

A. This is a judgment decision.

Q. Now, finally, the middle of the week after the 22nd when you got instructions to do no further assays, was that from Dr. Hill or Dr. Goldberg?

A. That was a communication of Dr. Goldberg, as I understood it, given to me by Dr. Hill.



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Q. And that was a direction that you agreed with, is that correct?

A. The reason for that was expalined to me and I could see those reasons were very relevant.

Q. Well, firstly, prior to this, you had no real experience with assaying tissue?

A. That's correct, yes, or body fluids.

Q. Very little experience with post mortem samples, correct?

A. Yes.

Q. No experience, as you testified, with forensic testing?

A. Yes.

Q. And very little experience with what had been called skyhigh levels ?

A. Yes.

Q. So, you would agree that that was a good direction in the middle of that week?

A. Yes, and the additional factor that -- I don't specifically remember whether it came up on this occasion but really at this particular time that police investigation was taking



Ellis
cr.ex. (Knazan)

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F14 2 place and it was taking place in this Hospital and,
3 so, obviously if you are going to do something
4 totally independently then it should really be done
5 outside the Hospital.

6 MR. KNAZAN: Thank you very much.

7 THE COMMISSIONER: Thank you, Mr.
8 Knazan?

9 Is it Mr. Arnold?

10 MR. ARNOLD: Yes, Mr. Commissioner.
11 Mr. Olah is before the Court of Appeal. He will be
12 here this afternoon. So, if you would wait until
13 then.

14 THE COMMISSIONER: Well, certainly
15 if we are still going.

16 MR. ARNOLD: Right.

17 MS. CRONK: I don't know, sir, at
18 this stage whether we will be carrying on with
19 Dr. Ellis this afternoon or not, but certainly if we
20 do there is no objection from us to standing Mr.
21 Olah down.

22 THE COMMISSIONER: No. No, I
23 don't want him to -- I know that Mr. Olah said that
24 he was content to -- well, we will see what happens.
25 If we are still going this afternoon the problem
is solved but if we aren't I don't want to keep Dr.



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Ellis here.

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MR. ARNOLD: Okay. If he doesn't

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make it in time he doesn't make it.

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THE COMMISSIONER: Yes, all right.

6

Mr. Connelly?

7

MR. CONNELLY: Yes, Mr. Commissioner.

8

Mr. Labow will be cross-examining Dr. Ellis and is
in the same position. I will undertake to phone him
at the break.

10

THE COMMISSIONER: Yes, all right.

11

MR. CONNELLY: Thank you.

12

THE COMMISSIONER: Mr. Tobias,

13

do you want to start now?

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MR. TOBIAS: Yes. I have very

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few short questions of the Doctor. It might be
helpful to me if we took our break now and I had my
break to prepare myself.

17

THE COMMISSIONER: Yes, all right.

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We will take twenty minutes then.

19

--- recess.

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EMT/cr

1 ---On resuming.

2 THE COMMISSIONER: Yes, Mr. Tobias?

3 MR. TOBIAS: Yes. Thank you, Mr.
4 Commissioner.

5 CROSS-EXAMINATION BY MR. TOBIAS:

6 Q. Dr. Ellis, I believe on
7 Friday you told Miss Cronk as of March 20th, 1981
8 you have no recollection before that date of ever
9 having heard of the case of Jordan Hines.

10 Do you recall that evidence?

11 A. The 20th of March?

12 Q. The 20th of March, 1981.

13 A. When was the 20th of March?
14 Was that the first, the ---

15 Q. The 20th of March, 1981 I
16 take it would have been the Friday, the day that you
17 ran the first tissue assays on Kevin Pacsai and
18 Jordan Hines.

19 A. Yes, okay.

20 Q. Do you recall specifically
21 this exchange? You were asked whether or not prior
22 to March 20th you had performed a digoxin assay on
23 any specimens from Jordan Hines, be it blood tissue
24 or body fluid and you said that you didn't know
25 because you hadn't looked over the 200 previous
entries.



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A. Yes.

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Q. You were then asked this

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question:

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"Perhaps you can help me with this.

6

Prior to March 20th do you have

7

recollection at all of having heard of

8

the case of Jordan Hines before?"

9

Your answer was "No".

10

A. The name I don't think - I
don't think rung any bells around that time. I know
it has since, but I don't think...

11

12

Q. All right. Fine. I take it

13

from that answer that it is possible you may have

14

heard of Jordan Hines but you have no recollection

15

today of having heard of the case prior to March

16

20th?

A. I have no recollection today.

17

Q. Okay. And prior to March

18

20th, 1981, had you reviewed the medical chart of

19

Jordan Hines?

A. I don't think so.

20

Q. I am sorry.

21

A. I don't think so unless it was

22

some analytical problem about - are you saying there

23

were digoxin entries for Jordan Hines?

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Q. My information is there were
no digoxin entries in his medical chart at all.

3

4

A. Yes. But were there any in
our book?

5

6

Q. But what I am specifically
interested in knowing at this point is whether you
had any recollection of having reviewed that chart
prior to March 20th, 1981?

7

8

9

A. I have no recollection of doing
that now.

10

11

Q. All right. Now with respect
to the assay that you did on March 20th, 1981, when
in point of time would you have attended at the
Virology Department to obtain samples?

12

13

14

A. When did I go to Virology?

15

Q. Yes.

16

A. During that week.

17

Q. All right. So it would have
been some time during the week of March 15th, 1981?

18

19

A. It was assayed on the 20th you
say?

20

Q. Yes. That was the Friday.

21

A. Yes, that was the Friday.

22

Yes. During that week.

23

Q. You would have picked it up

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some time during that week?

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A. Yes.

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Q. And the request itself, do you recall when the request for the assay to be run would have been made to you?

6

7

A. Not specifically, no, but I think it would have been after we had gotten the autopsy data, but I don't know.

8

9

10

Q. After you had received the autopsy data?

11

12

A. The autopsy data on Kevin Pacsai on Monday.

13

14

Q. All right. And that would have been either March 15th or 16th?

15

16

A. Thereabouts.

Q. Of 1981 because that was a Monday.

17

18

A. Yes.

19

20

21

Q. Is it possible at all that you could have been requested to do the assay on tissue of Hines prior to the week of March 15th or 16th? Is there any possibility of that or is that unlikely?

22

23

24

25

A. No, I think this was the first occasion on which anybody had even mentioned the idea



5 1
2 of tissues as such.

3 Q. All right. So we know it was
4 probably some time that week that the request was made
5 and it was some time that week that the samples were
6 picked up.

7 Now with respect to the choosing of
8 Jordan Hines specifically to run a tissue sample on,
9 your recollection is, as I understand it, that he was
10 chosen by someone else. That wasn't your decision?

11 A. H m-mm.

12 Q. There was someone at the
13 Hospital who had asked you to do that assay? Am
14 I correct?

15 A. Who had asked me to analyse
16 tissue samples, yes.

17 Q. From Jordan Hines?

18 A. I cannot specifically remember
19 the exact conversation and I cannot specifically
20 explain to you how the name of Whitehead appears in
21 the book or Hines appears in the book. I can explain
22 why Pacsai appears in the book but I cannot ---

23 Q. Well, all I am interested in,
24 Doctor, is this: Do you recall, can you help me, was
25 it your own specific independent decision, your choice,
to do the tissue assay on Jordan Hines? Did you



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3

decide to do it or did someone else ask you to do it?

4

A. I cannot specifically remember.

5

6

Q. All right. Is it possible it could have been your choice? You could have decided to do it?

7

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A. Well, having been told - having got to Virology and having been primarily interested with Pacsai, two samples - we know that two samples were taken in addition to that, to the Pacsai case - and so whether I chose them in Virology or exactly whether somebody specifically indicated those two cases I cannot - I don't have a specific recall.

14

15

16

17

Q. All right. I believe your evidence on Friday was that your recollection of how the tissue assays of Jordan Hines came to be was someone who previously asked you if you would do tissues.

18

A. Yes.

19

Q. Did you recall that evidence?

20

A. Yes.

21

22

23

24

25

Q. Now what I would like to know is this: when a request was made for you to do tissues, was it a general request or was it a specific request? In other words when you were asked if you would assay



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tissues, were you asked would you just generally assay
tissues, or were you asked by someone will you
specifically assay tissues with respect to certain
babies?

5

A. Well, the specific baby that
I remember being involved with at the time was Pacsai.

6

7

Q. All right. My question then
is this: Were you asked specifically will you do
tissue assays on Kevin Pacsai?

8

9

10

A. I cannot remember the specific
conversation.

11

12

Q. All right. That's fine. But
you do recall that the issue of tissue assays first
was suggested to you by someone else?

13

14

A. Yes.

15

16

Q. That wasn't something you
decided to do on your own?

17

A. No. That's right.

18

19

Q. All right. After that
conversation you attended at Virology to look at the
samples.

20

A. Yes.

21

22

Q. Did you ask for specific
samples or were you just handed samples?

23

A. My specific recall dating

24

25



1
2 directly back to that time is very limited. I think
3 that I mentioned previously that Dr. Cutz had given
4 some evidence and that that evidence suggested that
5 some samples were available in Virology it was my
6 understanding.

7 Q. Doctor, with respect to your
8 specific recall, if you don't recall, please tell me,
9 but I am not interested now in what evidence Dr.
10 Cutz had given or what evidence any other witness may
11 have given.

12 With respect to your own specific
13 recollection of the events, think back to when you
14 attended at Virology. Were the samples there all
15 ready for you and were they handed to you or did you
16 have to request samples from whoever it was you saw
17 at the Department of Virology?

18 A. I requested samples from the
19 people in Virology as far as I remember.

20 Q. All right. And do you recall
21 telling Miss Cronk on Friday - this is at Volume 49,
22 Mr. Commissioner. I am referring to page 947.
23 Starting at line 14:

24 "Q. I am sorry, were which cases?"
25 And your answer was this:

"A. Were cases of interest to you.



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"If we were to do something unusual that we had never done before we would normally ask for what we might call control samples, and we would usually try to analyse those control samples along with the samples of major interest. Okay.

Now my vague recollection is that these names were not selected at random by myself but somebody else asked me to go and view some tissue samples, particularly Pacsai, and also some others. The reason is not clear. Either as controls or they were of interest to them."

Does that help you in your recollection at all, Doctor?

A. Not really, no.

Q. All right. So you are still not clear as to whether or not the specific issues to be tested were suggested to you by someone else or chosen by yourself at random?

A. Yes.

Q. Let's go back then to when you attended at Virology. I believe you told me



1

2

samples were ready for you already or you had to
request them?

3

4

A. I just said I had to request
them.

5

6

Q. All right. And do you recall
whether you specified to them which samples you wanted?

7

8

A. I have said that I have no
specific recall.

9

10

Q. What would your normal practice
be?

11

12

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A. Well, my normal practice would
be that I would do something, and if I then did some
analyses and those analyses to me were totally
equivocal and I totally put them out of my mind, or
attempted to put them out - they became insignificant
after the 26th of March, or the 25th or the 26th of
March, 1981. They became irrelevant as far as I
was concerned. The analysis had not been completed
satisfactorily.

19

And then that event as far as I am
able went out of my mind from that time onwards.

20

21

Q. Well, would it be ---

22

A. And I can only reconstruct
what occurred.

23

24

25

Q. I'm sorry.



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2

A. Okay.

3

Q. All right. I appreciate that.

4

I appreciate all the problems of trying to recall,

5

and I am just trying to assist you.

6

Let's look at what your normal or

7

likely practice would have been had you attended at

8

Virology asking for samples and had you had to make

9

the request because they weren't ready. Is it likely

10

that you would have said to them give me some samples,

11

some virology samples on babies that died, or would

12

you have specified to the people in Virology which

samples you wanted?

13

A. I don't wish to speculate on

14

those ---

15

Q. I am not asking you to

16

speculate; I am asking you to advise me what your

17

A. Well, it wasn't my normal

18

practice to go to Virology. As far as I recall this

19

was almost - you know, probably one of the first

20

occasions that I had to go to Virology. It is not

21

our usual practice to obtain samples from Virology.

22

Q. All right. Does it come up

23

at all in the normal day to day course of what you

24

are doing at the Hospital where you might have to

25



1

2

attend at a department and ask for certain specimens?

3

A. Yes.

4

Q. All right. That does ---

5

A. Sometimes, yes.

6

7

Q. All right. And I take it
usually when you go to ask for those specimens you
have specimens in mind?

8

A. Yes.

9

10

11

12

13

14

Q. Now again with respect to the
particular instance of which we are talking, which
happened during the week of March 16th, would it have
been likely that you would have just gone to
Virology and vaguely asked for some specimens? You
certainly would have had to give them some indication
what it was you were looking for, wouldn't you?

15

A. Yes.

16

17

18

19

Q. All right. Does that help you
at all in recalling whether or not you specifically
identified the tissue with respect to babies Hines
and Pacsai or whether someone else made that decision?

20

A. No, it doesn't help me in
going directly back to that time.

21

22

Q. Okay. Fine.

23

Now you indicated to me earlier that
you had no recollection of having reviewed the medical

24

25



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chart of Jordan Hines prior to March 20th, 1981.

3

A. I have no specific recollection.

4

Q. You have no specific

5

recollection you told Miss Cronk on Friday of having

6

heard of the case before March 20th, 1981.

7

A. Hm-mm.

8

Q. What was the state of your

9

knowledge then on or about March 21st, 1981 as to

10

what drugs this child had been treated with in

11

Hospital?

12

A. I didn't know - I didn't know

13

what he had been treated with. As far as I can

14

recollect now I don't know what he was treated with.

15

I don't know what the dosage was, who had given it

16

to him or what he had been on.

17

Q. So you wouldn't have had

18

any recollection at that time of whether or not he

19

had been on digoxin?

20

A. Neither that patient nor

21

patient Whitehead that appears on the same page in

22

the book. I can't tell you right now who patient

23

Whitehead is.

24

Q. But do you agree with me

25

that you would have no knowledge in the Jordan Hines

case of whether or not he had been on digoxin?



1 A. If the route by which I got
2 to the Virology Department included conversations
3 with people in relation to samples, if it did, then
4 I might at that time have known whether he was on
5 digoxin or he wasn't.

6 Q. Well, Doctor, how would the
7 people in the Virology Department know whether Jordan
8 Hines was or was not on digoxin?

9 A. Well ---

10 Q. What knowledge would they have
11 had about Jordan Hines? Would they have reviewed his
12 medical chart?

13 A. But can you tell me whether
14 Whitehead was on or off digoxin or whether this child
15 was even on 4A at the time or whether this child was -
16 I cannot distinguish now between Hines and Whitehead.

17 Q. No, no. Doctor, I am not
18 asking you to distinguish between them. You can put
19 Whitehead out of your mind completely. Let's not
20 even talk about Whitehead. Let's talk about Hines.

21 Now you have told me that you have
22 no recollection of having heard of the case before
23 March 20th, 1981 and you have no recollection of
24 having reviewed the medical chart before March 20th,
25 1981.

Now I take it if you hadn't heard of



1

2

the case you most likely hadn't talked to any of the
clinicians about the case. Isn't that correct?

3

4

A. I cannot remember.

5

6

7

8

Q. Well, Doctor, had you spoken
to the clinicians about the case and had you had
discussions about it then you would have had to tell
Miss Cronk you had heard of it before March 20th, 1981.
Do you agree with that?

9

10

A. I guess so, yes. What point
are we coming to, really?

11

12

13

Q. Doctor, let me ask you this:
assuming that you had no knowledge of the Jordan Hines
case ---

14

15

16

17

18

A. All right.

19

20

21

Q. Prior to March 20th, and
assuming that you had no knowledge of whether or
not that child had been treated with digoxin, it might
be that you yourself would have consciously chosen
him as a control?

A. Consciously, no. No.

Q. So you are agreeing with me ---

A. I am sorry, can you rephrase
that again?

22

23

24

25

Q. All right. Let's phrase it
this way: In determining whether or not you choose



1

2

the Jordan Hines case as a control case ---

3

A. You implied a conscious

4

decision, yes.

5

Q. Wouldn't one of the pieces of
information you would have needed to have was whether
or not that child had been treated with digoxin?

6

7

A. One of the pieces that might

8

have been helpful to me, yes.

9

Q. How important would that have

10

been?

11

A. At that time? No, it is

12

just reconstruction.

13

Q. Well, Doctor, do you recall

14

telling your own counsel or the Hospital's counsel,

15

rather, Mr. Roland, on Friday that one of the things

16

you would have wanted to know in choosing a control

17

sample was whether or not that child had been on

18

digoxin.

Do you recall giving that evidence?

19

A. Yes.

20

THE COMMISSIONER: I thought he said that he
ordinarily would have wanted some who had been on
and some who had not. Isn't that right?

21

22

MR. TOBIAS: Yes, he did elaborate

23

on that later, Mr. Commissioner. Perhaps I can assist

24

25



1
2 the doctor by reading him back his evidence at Volume
3 49, page 1089.

4 Q. You were asked, Doctor,

5 "Q. Now if you are using a control
6 would you want samples of tissues from
7 babies' who were thought not to be on
8 digoxin, was that the kind of control?

9 A. Yes. Yes, you would. And you
10 would also want them ideally around the
11 same sort of age."

12 Do you recall giving that answer?

13 A. Yes.

14 Q. So clearly in choosing controls
15 you would want some babies who were not thought to
16 be on digoxin to use them as a control and compare
17 the assays on them with children who you had known
18 were on digoxin? Do you agree with that?

19 A. It would be a good policy, yes.

20 Q. Okay. Fine.

21 A. As I indicated.

22 Q. Yes. And it would appear, do
23 you not agree, you really didn't have any specific
24 information about whether or not Jordan Hines was
25 being treated with digoxin because you hadn't re-
viewed the chart?

A. Yes. I think that is correct.



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Q And in light of what you told Mr. Hunt this morning, that in all probability your recollection is it was someone else who chose Jordan Hines; do you agree with me given those two factors: one, that someone else chose them; and two, the factor that you had no knowledge about his clinical condition and whether or not he had been on digoxin, that it is unlikely that you in any event would have made a conscious decision to test for digoxin on Jordan Hines because you wanted to use him as a control?

A I am sorry, what was that, it was very reconstructed, wasn't it?

Q All right, I will make it shorter.

A Yes.

Q Given the facts that I have just brought out, don't you agree with me that it is unlikely that you would have been interested yourself in using the Jordan Hines' tissue as a control sample for running tissue assays on digoxin?

A It is unlikely or it is possible that I might have.

Q Fine, I will accept that.

Q Now at the time that the ---



H.2

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THE COMMISSIONER: I am sorry, were
they used as controls?

4

THE WITNESS: I cannot specifically
recollect why exactly the name of Jordan Hines and
the name of Whitehead come into ---

6

7

THE COMMISSIONER: I can tell you
why they come into it, because you tested the tissues.

8

9

THE WITNESS: Yes.

10

THE COMMISSIONER: That is why their
names come into your book.

11

THE WITNESS: Yes.

12

THE COMMISSIONER: Because you tested
their tissues.

13

14

THE WITNESS: Yes, okay.

15

THE COMMISSIONER: All I was asking is,
did you use them, have you any recollection that you
used them as controls, have you any recollection
having used them as controls and merely examined them
the same way you examined Pacsai?

16

17

18

19

THE WITNESS: I have no specific
recollection as to the exact circumstances under
which those two names were chosen, or those two samples
were chosen at that particular time.

20

21

22

23

THE COMMISSIONER: I just wonder from
the obvious bafflement of this witness if you would

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H.3

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have any information that you could feed to him that
might assist him, that's all?

3

4

MR. TOBIAS: No, I do not, Mr.

5

Commissioner.

6

THE COMMISSIONER: I don't think

7

really that you are going to stir up his memory any
better.

8

MR. TOBIAS: Well, no, indeed I was

9

about to move on entirely to another area, Mr.

10

Commissioner.

11

THE COMMISSIONER: Yes, all right.

12

MR. TOBIAS: Q With respect to the

13

running of the tests originally, all right, the fact

14

that the tests were run, was there any recent

15

documentation whatsoever documenting the request for
those tissue assays?

16

A. No.

17

Q So you have no knowledge of

18

any written requisitions or anything of that sort?

19

A. No.

20

Q You also told us I believe on

21

Friday that there were second tests run, tissue assays
done on March the 25th, 1981?

22

A. Uh-humm.

23

Q Why were those tests done, why

24

25



H.4

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were the tissues re-assayed on March 25th, 1981?

3

A. Because and I - because the

4

results on the Friday appeared to be illogical.

5

Q. Were they illogical, were the

6

tests run on the Friday, on March 20th, 1981, illogical
with respect to Jordan Hines?

7

A. No. They were illogical with

8

respect to Pacsai who we know had a high result in the
autopsy sample.

9

10

Q. All right, that explains I take

11

it why you would have re-run the assay on Pacsai. Why

12

re-run the assay on Hines?

13

A. Because if you are running one

14

you run the others.

15

Q. Why is that?

16

A. Because if you don't really

17

believe the results of the first assay then you try
and do them the next time.

18

Q. But you agree with me that there

19

was nothing in the results of the first assay

20

regarding Hines that would have made you suspicious

21

of it, or cause you to think that those results were
illogical?

22

A. No.

23

Q. Now, do you have any specific

24

25



H.5

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recollection of anyone asking you, in the case of
Jordan Hines, to re-do the assay on March 25th, 1981?

3

4

A. No.

5

6

Q. Do you have any recollection of
what might have been in your original instructions
which would have caused you to believe it was
important to re-assay that tissue sample on March 25th,
1981?

7

8

9

10

A. Not with respect to Jordan Hines,
no.

11

12

13

Q. Now you also told us on Friday,
I believe your evidence was that with respect to the
second test one of the problems that you had was that
you could not remember the exact methodology?

14

15

A. Yes.

16

17

Q. You did recall that the
homogenized sample was frozen and then thawed and then
re-assayed?

18

19

A. That note was written in my book,
yes.

20

21

Q. Do you generally keep notes on
the methodology that you use on assays?

22

A. Yes, we do, yes.

23

24

25

Q. These were highly unusual
assays that you were requested to do?



H.6

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A. Yes.

3

Q. In fact I think you told Miss

4

Cronk that never before had you been asked to do tissue
assays for digoxin?

5

A. That is correct.

6

Q. This was a precedent?

7

A. Yes.

8

Q. Did you not then keep notes of

9

the specific methodology with which the second assay
was done on March 25th, 1981?

10

A. No.

11

Q. Why?

12

A. Because as I indicated previously,
on March 25th, 1981, instructions had been given that
tissue testing should cease.

14

15

Q. I believe you said that those
instructions were given after March 25th?

16

17

A. No, I don't think I did, I don't
think I did.

18

19

Q. Then why did you disobey your
instructions if you had been told on March 25th not to
do the assays, why did you do them?

20

21

A. Because I believed that certain
things were pending. Just as on the 24th of March I
had spoken to Sergeant Press and given some indication

23

24

25



H.7

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that further tests would be undertaken. I regarded those results, the tissue samples, as kind of pending. Okay.

4

5

Q. Do you recall telling us on Friday that Dr. Hill specifically advised you that as it was now a police matter it was inappropriate for the Hospital to do any further testing?

6

7

8

A. That is correct.

9

10

Q. And your evidence today is that those instructions were given to you prior to running the second assay on March 25th, 1981?

11

12

A. That is correct.

13

Q. And regardless of those instructions you still saw fit to do them?

14

15

A. That is correct. Can I also remind you of one other factor?

16

Q. Yes, please do.

17

18

A. In respect of Miss Cronk's cross-examination, she asked me specifically in relation to the 20-hour delay that had occurred prior to the analysis. I said as far as I could tell her one possible reason why that might have occurred was that these samples had been thawed out the day before.

19

20

21

22

Q. All right, I believe you just told me one of the things that you indicated to

23

24

25



H.8

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Officer Press was that the results were still
pending?

3

4

A. Which results were still pending?

5

Q. The results of the tissue assays.

6

A. No, no, I didn't say that at
all.

7

8

Q. Well, what were you referring to
when you told me about your conversation with Sergeant
Press?

9

10

THE COMMISSIONER: Preliminary results
was I think what he said.

11

12

THE WITNESS: Well, this was
preliminary results with respect to the bowel contents,
the stomach contents and the chest fluid of Justin Cook,
it had nothing to do with these other samples.

13

14

15

16

MR. TOBIAS: Q. Doctor, the question
I want answered in short is why it was that you saw
fit on March 25th, 1981, to do the re-assay on Hines
when you had been specifically told that it was no
longer appropriate for the Hospital to be doing that
sort of thing? Was there some special curiosity you
had about this case?

17

18

19

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21

22

A. Not - you mean in relation to
Hines?

23

24

25

Q. Yes?



H.9

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A. No, there was not.

3

4

Q. Was there some special concern
you had in relation to Hines?

5

A. No.

6

Q. Was there some special concern
that you had with respect to Pacsai, or some special --

7

A. Yes, there was.

8

9

Q. Is that why you re-did the assay
on Hines even though you had been told not to?

10

11

A. That was why that batch was
repeated on that particular day.

12

13

14

15

Q. All I want to know is this, and
perhaps this is the shortest way to deal with it. Since
you had decided in your own mind that you were going
to do it on Pacsai, you did it on Hines as well, is
that fair?

16

17

18

19

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A. That would be fair to say. One
consideration in my mind at that time in relation to
the bowel contents, the stomach contents and these
materials that were around the lab was the stability
of materials in these samples, and therefore if I
half analyze something and there was a possibility
that this sample might deteriorate before further
analysis could be performed, then the logical
procedure then was to at least get to a point where I



H.10

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had some kind of confidence in the results. That is why that additional testing took place even after that instruction.

Q. You indicated on Friday that the reporting with respect to the subsequent reporting of the assays done on March 20th and March 25th, 1981, that your recollection was that you did not report those results. You recall giving that evidence to Miss Cronk, do you not?

A. In respect of the tissue samples assayed on those two dates?

Q. Yes, the tissue samples specifically with respect to Hines and Pacsai?

A. Yes.

Q. And that the reason that they were not reported was because you felt they were unreliable?

A. That is correct.

Q. And you gave us your reasons for thinking that?

A. Yes.

Q. At any time after March 25th, 1981, did anyone ever inquire from you, and I am referring now specifically to anyone at the Hospital, did anyone ever inquire as to what the results were?



Hi.11

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A. The results of Hines and Pacsai?

3

Q. Yes, the assays that you had

4

been requested to do?

5

A. No.

6

Q. So there was never any

subsequent follow-up, was there?

7

A. No.

8

Q. And therefore, whoever had

9

asked you initially to undertake those tissue samples

10

never made any further request from you, or any

11

investigation with respect to what those assays had

12

shown?

13

A. Not to my recollection.

14

Q. All right.

15

A. But if they had made that then

16

I would have told them, I would have expressed the

17

same confidence in those results that I have expressed
to you.

18

Q. Yes.

19

A. That I have no confidence in

20

those results.

21

Q. And that is important and you

22

surely would remember such a subsequent conversation,
wouldn't you?

23

A. I wouldn't necessarily.

24

25



H.12

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Q. I am sorry?

3

A. I wouldn't have done necessarily.

4

Q. Is it important, or isn't it
important?

5

6

A. It is important to you, but it
wasn't important to me.

7

8

9

10

11

Q. I am asking you whether it was
important to you, Doctor, with respect to what you
had been asked to do, that you had equivocal results
that you had no confidence in, isn't that a pretty
important factor in your own mind as a biochemist?

12

A. No.

13

Q. No?

14

A. Not really, no.

15

16

Q. Did you consider it strange at
the time, or do you consider it strange today, that
there was no follow-up on those results?

17

18

A. Follow-up on who and for what
purpose?

19

20

Q. Doctor, with respect, I am
the one asking the questions. Let me help you this way.

21

A. All right.

22

Q. Do you agree with me that this
was the first time such a request had been made?

23

A. Yes.

24

25



H.13

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Q. A highly unusual request?

3

A. Yes.

4

5

Q. And that must have seemed a little bit strange to you at the time, didn't it?

6

7

A. No, no, because it was in respect of Kevin Pacsai and the child had died under circumstances that were not totally explained.

8

9

10

Q. All right. Pacsai you had already had the results of the autopsy, so you knew that there were high digoxin readings?

11

A. Yes.

12

Q. That must have concerned you?

13

A. Yes, sure it did.

14

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Q. And therefore you found that although the request for the tissue assays were somewhat novel they were not particularly strange, you could understand why you might be asked to do those assays in light of the high dig. levels on autopsy; do you agree with that?

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A. Yes, that is correct.

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Q. And yet although you didn't report back to whoever it was who asked you to do the samples, they at no time to your recollection made any request of you as to what you found?

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A. No.

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Q. Do you not find that strange?

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A. Not really, no.

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MR. TOBIAS: Those are all my questions, Mr. Commissioner. Thank you.

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THE COMMISSIONER: Thank you, Mr. Tobias.

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Mr. Shinehoft?

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CROSS-EXAMINATION BY MR. SHINEHOFT:

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Q. Mr. Ellis, my name is Jack Shinehoft and I represent the parents of the Baby Kevin Pacsai.

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A. Yes.

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Q. Doctor, you indicated previously that for the convenience of reporting when you were doing these digoxin levels: "That the figure of 0.2 was used in my laboratory at this time", is that correct?

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A. Yes.

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Q. And that was the lowest level that we reported?

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A. Yes.

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Q. And would you also agree with me, Doctor, would you not, that 0.5 is what is considered the bottom of the therapeutic level for the drug?

A. At that time, yes.



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Q. Could you tell me, Doctor, when would you come across levels of 0.0 to firstly 0.2?

A. I am sorry, 0.0 to --- ?

Q. To 0.2?

A. I think ---

THE COMMISSIONER: 0.2 is the lowest you can report.

THE WITNESS: This was the lowest we would normally report. It in other words, if we got 0.1 we may well report it as under 0.2.

MR. SHINEHOFT: Q. I see. You would get levels of 0.2 to 0.5, would you not?

A. We would get them?

Q. Yes.

A. Well, the computer would produce even 0.1.

Q. Then that would be reported as?

A. Under 0.2.

Q. You would get readings of 0.2 to a reading of 0.5?

A. Yes.

Q. Would that be a fairly common situation?

A. Not terribly common, no, I don't think.



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Q. And would you get these readings,
or these levels on children who had never been
prescribed digoxin?

A. Did we have specific knowledge
as to whether these children had been prescribed the
drug?

Q. Yes, yes, Doctor?

A. In respect of which individual
case?

Q. No, I am just talking in general.

A. In general?

Q. Yes, in general, would you ever
have a reading, for example, of 0.3 or 0.5, or 0.4 on
a baby that had not been prescribed digoxin?

THE COMMISSIONER: The simple answer
is there wouldn't have been any test on any child
until after this thing blew up on the weekend.

MR. SHINEHOFT: No.

THE COMMISSIONER: At least I would be
surprised. Do you ever remember being asked to test
any child?

THE WITNESS: We would not have
expected samples under normal circumstances from
children who had not been prescribed digoxin. But we
would have no way of knowing on receipt of that sample
whether or not the digoxin had or had not been
prescribed.



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THE COMMISSIONER: Far better to hold these until the tests come out for those children after this weekend.

MR. SHINEHOFT: Yes.

THE COMMISSIONER: Where there may well have been. That will be Dr. Phillips I suspect.

MR. SHINEHOFT: Yes. Perhaps you don't feel qualified to answer this question and if you don't, Doctor, please tell me, about testing done subsequent to that weekend, the weekend of March 21st, 1981 and the question of digoxin levels of children who have perhaps not been prescribed that drug.

THE WITNESS: Yes.

MR. SHINEHOFT: Q. Are you aware of any studies that have been done at the Hospital?

THE COMMISSIONER: But there have been not studies, every child was tested automatically, was it not?

MR. SHINEHOFT: Tested.

THE WITNESS: That's right, yes. In fact, on the weekend of March 22nd or thereabouts, on that particular weekend all the children were.

MR. SHINEHOFT: Q. Yes, I understand that. I understand Dr. Phillips will be coming here



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to give evidence in that regard?

A. Okay. But there were also some other children that I alluded to in the preliminary hearing.

Q. There were?

A. Yes, I was asked about.

Q. Now, Doctor, you also gave evidence that the reason why you would not over-dilute a sample I believe was to prevent the multiplier effect of any potential inaccuracy, is that correct?

A. We would not dilute a sample without a preliminary undiluted analysis in the normal way of doing things.

Q. Right. But you wouldn't go from neat to 1 to 20, for example, without maybe going to 1 to 10, is that correct?

A. That's quite likely.

Q. And the reason for that is that if there were an error then the error would not be multiplied 20 times but only 10 times, is that correct?

A. Yes. I would be better to do it that way.

Q. Doctor, if you had a diluted sample that showed that the results were greater than



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what could be calibrated or recorded, could you not dilute that dilution?

A. Yes, you could.

Q. And in Pacsai you found that you only had one test tube, correct, to do the sample?

A. We only had one test tube, yes, okay.

Q. And the test came back at greater than 10, the result came back, the assay came back.

A. Oh, okay, sorry. In respect of Pacsai - are you talking about the antemortem sample?

Q. I'm talking about the antemortem sample.

A. In the CBC tube that there was very little serum with.

Q. Right.

A. Okay, we had reason to believe from the requisition the child might have had digoxin toxicity?

Q. Yes, that is correct, Doctor.

A. Then we took the material available to us that was 50 microlitres, if I'm right,



1
2 without looking at the book, 50 microlitres in one
3 tube, 25 microlitres in the other and we had no
4 further sample available.

5 So, in that particular case before we
6 had even obtained a result we had used that sample.
7 There was no diluted sample to use.

8 Q. Well, when you get a test
9 result back is all the blood in the sample used?

10 A. Under most circumstances, no.

11 Q. Well then, can you not, Doctor,
12 if you get an unsatisfactory result or a result
13 that cannot be accurately given redilute that sample
and test it again to come up with another result?

14 A. In many instances, yes, but not
15 in the specific instance that you are referring to.

16 Q. Why not?

17 A. Because the amount of sample
18 was very, very limited; very, very limited, it wasn't
19 actually run on a dilution of one in 20 or one in a
20 hundred or whatever number you would like to use, it
wasn't actually run that way.

21 Q. Well, how was it run, Doctor?

22 A. Well, it was run by taking one
23 tube of 50 microlitres of serum, okay, and one tube
24 of 25 microlitres of serum and then there was
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I.5

nothing left.

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Q. Okay.

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A. Okay, and then we proceeded to

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do the analysis. And then the results on those two

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tubes were presented to us. So, we then knew that

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it was going to be high. That wasn't of any help

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to go back to any diluted sample because there wasn't
any sample.

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Q. Well, Doctor, from what you

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have just said you could run two samples, one with

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50 microlitres and one with 25 microlitres, is that

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correct?

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A. That's right. During the

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process of that run that serum sample in that

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particular instance would have been consumed or

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disposed of in the normal process of the analysis.

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Q. Well, I can understand the

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25 microlitre one being used up but are you saying

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that the 50 microlitre sample was completely used up
as well?

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A. Yes.

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Q. Well, I don't understand how

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it works that it could use twice as much sample on

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the same assay. Could you explain that to me,

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Doctor?

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A. It is our normal practice to analyze two amounts of a serum sample supplied to us in the analysis; two amounts of 50 microlitres each in our normal way of doing things. There is normally some serum left in the original tube that was supplied to us, which isn't touched any further. Once the two 50 microlitres have been obtained that sample is still available to us for anything that we would like to do later on that sample. In respect of having transferred the 50 microlitres or the 25 microlitre sample to the radioimmunoassay tube, the subsequent process of analysis means that that sample is consumed by the process and then that particular amount is no longer available to us.

Now, we can either be in a situation where there is some serum left in a tube that we started out with way back or there isn't any because we've used it and in respect of Pacsai we had used it.

Q. So, you never run the test completely and then have some left over after you have run the test, is that correct?

A. We frequently do if a large amount of serum sample has been provided to us.

Q. I see. No, I meant once it is in the RIA tube, the testing tube, you don't have a



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sample of serum that is left over after the RIA process is completed?

A. No, the addition of the charcoal essentially destroys the serum.

Q. Okay, I understand now.

A. In that process, that separation process.

Q. You also as well, Doctor, gave evidence about the computer extrapolating a number or a reading.

A. Yes.

Q. Where there is an insufficient sample or where the reading is such that it is a greater than reading, is that correct?

A. Yes.

Q. Have you ever had a situation, Doctor, where the computer has extrapolated a reading and then you have redone the test with further samples that you have had at a different dilution? Has that ever happened, Doctor?

A. Yes.

Q. And have you ever compared the extrapolated figure that the computer gives to the actual figure that you have determined as a result of that second assay or sample?



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A. Yes.

Q. Have you correlated those two figures?

A. We have inspected those two figures, yes.

Q. And could you give me some idea as to how accurate the extrapolations of the computer are?

A. I would say very close to the top standard. The extrapolated value is probably fairly close to the true value. So, you cannot go very far along that. It is a slippery road once you get above the top standard.

Q. So, in Kevin Pacsai's case I believe the computer extrapolated an ante mortem of 16, is that correct?

A. There was some question about this on Friday and I cannot tell you.

THE COMMISSIONER: Where did you get that figure?

MR. SHINEHOFT: I believe it is from your notes, Doctor.

MS. CRONK: It is page 23, sir, of Tab 45.

THE COMMISSIONER: Oh, yes, I see it.



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MR. SHINEHOFT: Q. Have you got that
in front of you, Doctor?

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THE COMMISSIONER: It is 16 on the
first one, Item 4.

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THE WITNESS: I'm sorry, page?

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THE COMMISSIONER: Page 23 of Tab 45.

8

THE WITNESS: Ah, the result of 16,
yes.

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MR. SHINEHOFT: Q. Yes. Do you see,
Doctor, there is a 16.0 number there?

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A. Yes.

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Q. I believe you said that that
was the figure that was extrapolated by the computer?

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A. I think I said that that
possibly could have been a figure extrapolated by the
computer but I wasn't certain.

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Q. Well, can you give me any other
explanation as to why that figure would be there,
Doctor?

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A. Well, Doctor, it might have
been that the computer did produce a figure of 16,
that's one possible reason.

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Q. Well, presumably that information
would still be in the computer today.

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A. No, no it wouldn't.



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Q. No. But assuming that that is the figure that is extrapolated by the computer, it is your evidence, Doctor, that it is somewhat accurate or related to the true antemortem sample?

A. No.

THE COMMISSIONER: Too far away.

THE WITNESS: Too far away from the top standard.

THE COMMISSIONER: This was done neat?

THE WITNESS: Yes, it was.

THE COMMISSIONER: So that 16.0 is at least 11 points over the top?

THE WITNESS: Yes.

MR. SHINEHOFT: Right.

THE WITNESS: If that had been 5.1.

MR. SHINEHOFT: Q. Right.

A. You know, 5.0 was our expected, then I would have accepted, you know...

Q. It would have been a little more accurate?

A. A little more reasonable. Can I say perhaps that with other assays, if even more than this value is obtained, if the sample is extremely high, even negative answers can be obtained.



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Q. Yes, I believe you did give evidence to that effect, Doctor. So, when you get into the realm of, like, at least three times more than the top standard you decrease the reliability of that number, is that right?

A. You decrease the reliability as soon as you step beyond the top standard.

Q. And have your tests that you have done with samples that have subsequently been analyzed to be specific indicated that that is in fact the case that where you get very much beyond the top standard that the number is somewhat inaccurate?

A. Yes.

Q. Thank you, Doctor.

Now, I believe you gave evidence on Friday, Doctor, as far as the qualification of the sample of greater than 10. Correct me if I'm wrong, I am referring to Volume 49 at page 848, line 7 that the only slight rider I would have re the sample of greater than 10 is that we had analyzed only a single tube of one dilution, normally they do two. So, in that sense it was a little less reliable than a regular assay, is that correct?

A. Yes. Well, there are two tubes there, one being on the dilution.



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Q. Yes, but it is not the number of tubes that you normally have if you have unlimited sample available?

A. No.

Q. And is it correct in saying that that is the only qualification that you put on that level?

A. The level of this individual sample?

Q. This individual sample that you have taken.

A. This was a CBC tube?

Q. Yes.

A. Okay. We have to include that in our consideration.

Q. But you also gave evidence that you did some further analysis with other samples with CBC tubes and you came to the conclusion I believe that the EDTA did not skew or affect the results of the assay, is that correct?

A. Yes.

Q. So, you went further on to say that we were unable to be as thorough as usual in respect of duplicates?

A. Yes.



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Q. And that is the one qualification you put on the assay that you have done?

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A. Are you asking me for other qualifications?

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Q. Yes, if you have any.

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A. As of now?

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Q. Yes.

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A. Or as of then?

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Q. Well, both, Doctor. You did give a number of concerns that you had at the time.

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A. Yes.

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Q. And I believe those concerns have pretty well been alleviated, is that correct?

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A. In respect of EDTA, yes. There is one other issue that this sample did not arrive at the laboratory in a normal mechanism. If my recollection serves me correctly it went to hematology and then the remaining material from hematology came to the laboratory. So, that is somewhat unusual.

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Q. Well, would it be unusual to the extent that it might alter the accuracy of the results, Doctor?

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A. That is possible. I don't know what might have happened to it in hematology, for example.

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Q. All right.

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A. Whether evaporation was permitted
or how the sample had been stored.

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Q. Right.

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A. You know, you are just asking
me right now but I didn't think of this on previous
occasions.

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Q. I want to know if you have
come to any subsequent conclusions about that sample
and you are indicating that the route that it came
to you by was not the normal route.

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A. It is a little bit unusual,

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yes.

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Q. Is there any other qualifications
that you may have as far as that sample is concerned?

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A. Nothing that I can think of
right now.

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Q. You also gave evidence,
Doctor, that you sent a sample to Mount Sinai for an
analysis there and they came back with the reading
of 112 nanograms per millilitre. Is that correct,
Doctor?

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A. Are you referring to this
sample or an autopsy sample?

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Q. Oh, it may be an autopsy sample.

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A. Yes.

Q. Yes, I'm sorry. That was the sample that you analyzed to be about 26, is that correct?

A. Yes.

Q. And it came back at 112?

A. Yes.

Q. And is there any reason that you can give as to why there was such a discrepancy between the calculations you made and the calculations that came back from the Mount Sinai?

A. I think I tried to give an explanation for this on Friday.

THE COMMISSIONER: It's bad enough having Mr. Tobias constantly referring to Friday. I would be delighted if you would like to continue these sittings on Friday but I'm not going to be here. It was Thursday I think.

THE WITNESS: Oh, sorry, yes, thank you.



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Q. And what was that explanation, doctor, as to -- you agree there is a tremendous difference in the results --

A. Yes.

Q. -- is there not?

A. Yes. Still, they were using a different antibody from a different animal. They were using a different separation technique. The material had come from a totally different manufacturer.

It was -- the sample that went to Mt. Sinai was an autopsy sample and I think -- I don't know how much experience they have with autopsy samples, but I think that this was discussed later and we just attributed it to the differences between the antibodies and separation techniques and different methods.

Q. And on a theoretical basis, doctor --

A. Yes, on a theoretical basis.

Q. If you had a sample that measured to be, we will say an ante mortem sample of 10 at the HSC by your methods, theoretically it should measure at Mt. Sinai as 10 as well, should it



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not?

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A. Yes. And under normal circumstances, yes, that is right.

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Q. And have you done prior to this or subsequent to this control testing for things like digoxin with the Mt. Sinai Hospital or other hospitals to determine the relative accuracy of the various testing methods?

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A. Subsequent tests have been done, not with respect to Mt. Sinai, to my recollection, but with respect to other methods.

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Q. And have the results generally been the same whether they be tested at your Hospital or other hospitals?

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A. Are you referring to autopsy samples or normal samples?

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A. With respect to normal samples and quality control materials that are distributed around the province, our results are very comparable to results obtained by other hospitals with respect to quality control samples.

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Q. What about post mortem samples?

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A. Post mortem samples, the only post mortem samples that I am aware of



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in addition to this particular one are some that were sent to the Forensic Sciences Laboratories, and Dr. Soldin has previously testified concerning those results before the Commission.

Q. Yes.

A. In relation to two different methods. He has also described those, and there are discrepancies in autopsy samples between different methods.

Q. But theoretically there shouldn't be; is that correct, doctor, in an ideal world?

A. In an ideal world there shouldn't be, no. If everybody is measuring exactly the same thing; namely, digoxin.

Q. Doctor, did you come to any conclusions as to the reliability of the RIA testing method on tissue samples for digoxin?

A. The tissue?

Q. The reliability of the RIA testing method on tissue samples for digoxin.

A. You mean in relation to the assays that we ourselves had done on the 20th and 25th of March?

Q. Yes.

A. Yes, I did.



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Q. First of all generally
and then secondly I am going to ask you about
specifically Kevin Pacsai.

First of all generally as far as
your testing methods are concerned.

A. We had no previous ex-
perience of analyzing any tissue samples for digoxin
to my knowledge prior to this occasion.

We are often asked by clinicians
or other people to assay samples that we had never
attempted to assay before, and may very well indicate
to them that we will try the material that they are
interested in in our own assay that we have faith
in and we will see what happens. And depending upon
what happens we will then convey results to them or
not convey results to them or tell them -- or come
to some conclusion about whether our assay method
really works on those samples as opposed to our
usual samples.

Q. Well, do you feel that the
results of the tissue samples done specifically on
the child Kevin Pacsai were consistent with his post
mortem digoxin levels?

A. The results on the 20th
of March which I think showed under 0.2?



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Q. All your results. You did some on the 21st of March, is it, that you did some and some on the 25th?

THE COMMISSIONER: Some on the 20th and some on the --

THE WITNESS: I have no confidence in either of those results. I don't know --

MR. SHINEHOFT: Q. So the conclusion you came to presumably would be that the RIA testing method is unreliable?

A. The RIA method as practised by us on those two occasions in the way that we did it, however we did it, in my view was unreliable at that time.

Now having said that there are subsequent -- I have subsequently read some literature and that suggests that extraction procedures should be adopted for this kind of material and we had not used that.

Q. So what you are saying now, doctor, is presumably if you had to do it over again --

A. Yes.

Q. -- with the knowledge and understanding that you have now --



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A. Yes.

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Q. -- you would do it

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differently?

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A. Yes, very much so.

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Q. And that if you did it

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differently then the results might very well be more
in line with what the serum levels would report;

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is that right?

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A. If we did it differently

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I would expect to get different answers from the
conflicting answers that we obtained before.

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Q. But the material and the

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literature that you have read, doctor, would seem
to indicate that you could have valid results on

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tissue samples if done a different way?

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A. Oh, done a different way?

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Q. So you are of the opinion

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that you place no value or merit in these sample

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results that you did obtain on the tissue of Kevin

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Pacsai? Is that correct, doctor?

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A. On the 20th and 25th, yes.

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MR. SHINEHOFT: Thank you very
much, doctor. I have no further questions.

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MR. TOBIAS: Mr. Commissioner, a
highly unusual request. I will use the same candor

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that Mr. Scott used when he told you he was just trying to get out of the witness what the witness had told him the hall previously.

THE COMMISSIONER: Yes. All right.

MR. TOBIAS: I forgot to ask one question --

THE COMMISSIONER: All right. Ask it now then.

MR. TOBIAS: I would like to ask it now so we don't get into the problem of having to call more reply evidence.

THE COMMISSIONER: Yes. All right.

FURTHER CROSS-EXAMINATION BY MR. TOBIAS:

Q. Dr. Ellis, I should have asked you whether you know Dr. Becker in the Pathology Department?

A. Yes, I do.

Q. Do you know Dr. Sugar who at one time was in the Pathology Department?

A. Dr. Sugar?

Q. Yes.

THE COMMISSIONER: A female, I believe.

MR. TOBIAS: Q. A female doctor.

A. Is that right?



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MS. CRONK: I don't have a list,
doctor, I promise you.

THE WITNESS: Nobody remembered the
tatty bit of paper that I showed you this morning.

THE COMMISSIONER: Apparently he
doesn't know Dr. Sugar.

MR. TOBIAS: Q. Do you recall if
it was Dr. Becker who might have specifically asked
you to do digoxin assays on the tissue of Jordan
Hines?

A. No. I can't specifically
tell you that it was Dr. -- recall whether it was
Dr. Becker, but a Dr. Sugar that I didn't really
know anything about as of this morning may well have
been in the Pathology Department at that time.

Q. She may well have been
in the Pathology Department at that time. Let me
understand your answer. You are telling me you
can't recall whether Dr. Becker might or might not
have made the request or that you have no recollection
of his having made the request?

A. That is correct.

Q. I put two alternatives to
you.

A. I'm sorry.



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Q. Can you tell me which one
is correct?

A. I have no recollection of
him having made that request to me.

Q. All right. Do you have
any recollection of a Dr. Sugar having made it to you?

I take it no since you weren't
aware whether or not she was in the Pathology
Department.

THE COMMISSIONER: Or what her
sex was.

MR. TOBIAS: Yes.

Q. Am I correct that you
would have no recollection of her having made the
request?

A. I have no recollection of
her having made the request.

MR. TOBIAS: All right. Thank you,
doctor.

THE COMMISSIONER: Now, Mr. Gouge.

MR. GRANT: It is Grant, sir.

THE COMMISSIONER: Grant, yes,
sorry.

MR. GRANT: We have no questions
of Dr. Ellis in re-examination.



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THE COMMISSIONER: All right.

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Thank you.

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Miss Cronk?

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MS. CRONK: Mr. Commissioner, I

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raise this issue only in light of what was said
this morning.

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I obviously am prepared to start
now. I am equally interested in having the doctor's
examination completed as soon as possible.

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10

I am mindful of the fact that

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Mr. Olah and Mr. Labow have indicated they will be
here this afternoon. I make this suggestion only

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13

for that purpose: If you would like to take your
afternoon break now, sir, they would then have an

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opportunity to cross-examine the witness soon after
lunch.

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THE COMMISSIONER: I am going to

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get a terrible reputation. Supposing I make it
for an hour and a half to 2:15 and they don't show
up because they are used to coming at 2:30. Then
what do we do then?

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MS. CRONK: I would suggest that
they are represented here and others can attempt to
reach them over the noonhour.

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THE COMMISSIONER: All right. We

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will take the break then until 2:15. Would a word
to the wise be sufficient to pass on? If they are
here at 2:15 they will be heard and if they are not
they won't.

MS. CRONK: Thank you, sir.

--- luncheon recess.



AA/DM/ak

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---Upon resuming at 2:15 p.m.

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THE COMMISSIONER: Well, are we any

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further ahead? What do you say?

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MR. ARNOLD: Mr. Commissioner, Mr. Olah

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is not going to make it, so we don't have any questions.

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THE COMMISSIONER: Thank you. It

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looks as though neither Mr. Labow nor --- Yes,

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Mr. Labow?

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MR. LABOW: We have no questions,

Mr. Commissioner.

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THE COMMISSIONER: Thank you. Now

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you have delayed your re-examination just about as

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long as I will permit.

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MS. CRONK: Well I do have some

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questions, sir.

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THE COMMISSIONER: Yes, all right.

RE-DIRECT EXAMINATION BY MS. CRONK:

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Q. But not many, Dr. Ellis, I

18

assure you.

19

Dr. Ellis, do you recall last Thursday

20

Miss Symes suggesting to you, during the course of

21

your discussion with her, that there were a number

22

of examples reflected in your digoxin books maintained

23

in your laboratory regarding children at the Hospital

24

for Sick Children in respect of whom digoxin levels

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had been recorded in excess of therapeutic levels;
do you recall that?

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A. Yes.

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Q. And those were living children,
that is children who presumably had their digoxin
therapy adjusted and survived the experience.

8

A. Yes.

9

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11

Q. Your attention was drawn
particularly by Miss Symes to the case of a patient
called Husbands whose digoxin level was recorded at
7.8 nanograms; do you recall that?

12

A. Not that specifically but ---

13

14

Q. Well to refresh your memory,
Miss Symes asked you to look at two specific references
in one of the digoxin books.

15

16

A. Yes.

17

18

Q. One was in respect of a
patient called Husbands, whose level ultimately on
dilution was recorded at 7.8 nanograms.

19

A. Yes.

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21

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23

Q. The second patient whose
attention you were specifically drawn to was a
patient by the name of Rene whose level was reported
at 7 nanograms, do you recall that, that exchange?

24

A. I recollect Husbands now, yes.

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Q. I am sure there are others that we can look to specifically in your books, Doctor, but am I correct as a basic proposition that in any given case if a sample is taken too close to the time at which the last dose of digoxin was administered the digoxin reading or level may be falsely elevated when the assay is conducted?

A. It may be, yes.

Q. That could, if that were the case, explain the Husbands level or the Rene level of 7 nanograms that we looked at if their samples had been taken too close to the time at which the last dose of digoxin had been administered?

A. It could do, yes.

Q. And elevated levels we have heard can also result if the patient involved was suffering from acute renal failure, or pronounced kidney dysfunction at the time that the sample was taken, do you agree with that?

A. Yes.

Q. We know in the case of Kevin Pacsai with whom you had some involvement, that the sample was not taken in close proximity in point of time to the point when the last dose of digoxin was administered; do you agree with that?



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A. Yes.

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A. Yes.

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A. Yes.

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Q. And similarly ---

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A. Well, do we know that?

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Q. I am sorry, the evidence

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suggests ---

A. Do we know for sure that she had not received digoxin four days prior to her death?

THE COMMISSIONER: That is what this Inquiry is all about.

THE WITNESS: Well, exactly that was why ---



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3 THE COMMISSIONER: That is a very
4 good question.

5 MS. CRONK: I am sorry.

6 Q. Doctor, in the sense that no
7 digoxin was prescribed and administered for Janice
8 Estrella.

9 A. Yes.

10 Q. In the four days prior to her
11 death, that does not appear to be the explanation
12 that a prescribed dose of digoxin was administered
13 too close in point of time to the date at which the
14 sample was taken?

15 A. That does not appear to be the
16 reason in that case.

17 Q. And similarly in the case of
18 Justin Cook, who the evidence suggests never received,
19 at least was not prescribed digoxin at the
20 Hosiptal for Sick Children, that does not appear to
21 be the explanation for his level?

22 A. It would not appear to be an
23 explanation, no.

24 Q. I take it, Doctor, that in
25 respect of the clinical condition of those three
children, Pacsai, Estrella and Cook, and that is
whether or not any at the time of their deaths were



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3 experiencing acute or pronounced renal dysfunction,
4 that that is a matter in respect of which you would
5 defer to the clinicians who were involved?

6 A. Yes. The only additional
7 evidence is that we have high levels in Estrella
8 prior to the time of death, you know, while she was
9 still alive. I think that puts her in a slightly
10 different position from Allana Miller where we have
11 low levels prior to the time of death.

12 Q. I was directing my attention,
13 and I thought yours, for the moment, to Estrella,
14 Pacsai and Cook and we know that we have antemortem
15 levels on all three of those children. I was only
16 suggesting to you, and perhaps I am incorrect, that
17 you would not have any particular knowledge as to
18 the state of their kidney function at the time those
19 samples were taken?

20 A. No.

21 Q. All right, thank you, Doctor.
22 Doctor, do you recall as well - well, perhaps one
23 further point; may we assume a situation for the
24 moment where indeed a sample is taken too close in
25 point of time to the time at which the last dose of
digoxin was administered, I would ask you to make
that assumption.



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A. Okay.

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Q. You told Miss Symes that although you couldn't recall a specific or an individual instance where that had happened you have seen levels elevated as high as 10 in that set of circumstances, do I have that correctly?

8

A. Oh, yes.

9

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11

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Q. And in that situation, Doctor, that is where a sample is taken too soon after the last dose, have you ever seen a level elevated to the extent of 26 nanograms; leaving aside the case of Kevin Pacsai?

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A. I would have to make reference to the list of results that I gave to the Preliminary Hearing against Susan Nelles where a large number of analysis that had been performed exceeded 5.0, after the time of direct relevance to this present Inquiry. But that subsequently turned out to be a deduction anyway taken too close to the previous dose. Are you familiar with the list to which I refer?

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Q. Yes.

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A. Or the contents of that list.

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Q. Perhaps I can put the question then in a time frame for you. I take it that by virtue of your lengthy experience in the laboratories



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at the Hospital, and taking digoxin levels and performing digoxin assays, on numerous occasions you have had situations where further enquiry offered the explanation that an elevated level was the result by virtue of the fact that the sample had been taken prematurely?

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A. Yes, in many cases.

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Q. And sitting here today, Doctor, to the best of your recollection, where that set of circumstances applied or where the sample was taken prematurely, do you have any recollection at all of ever having seen the elevated level caused for that reason in the vicinity of, for example, the levels that we have seen in Cook, Miller, 68, 72, 78 nanograms levels that high?

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A. I cannot say specifically whether we were - we were diluting samples as extensively at the time prior to these events compared with afterwards. So there may be a greater than 5 result there that was not followed up in 1978, okay, which might have been just as high as the numbers that you are pointing out to me, but I cannot say that specifically.

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Q. I take it, Doctor, then that you have no specific recollection one way or the



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other of having seen levels that high for that reason?

A. No specific recollection prior to this time, prior to August, 1980, for example?

Q. That is right, Doctor.

A. Yes, I have no specific recollection of any numbers prior to that time.

Q. And indeed during the time period with which we are concerned, that is from July 1980 through to the end of March 1981?

A. The end of March 1981?

Q. Yes.

A. I cannot remember the first items on the list that I read out at the Preliminary Hearing. I don't know when those occurred, but certainly if you recall there were a number of maybe 15 or 17 names that I gave evidence on that had occurred after, about I think the 22nd of March or thereabouts until the time that I testified on approximately the 9th of February, 1982.

Q. All right.

A. Between that time period there had been that many occasions when high results have been obtained.

Q. And Doctor, that evidence is available to us?



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A. Yes.

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Q. And we can simply look at it and see what the reported levels were, because you did indicate what the levels in fact had been on those samples?

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A. Yes.

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Q. Doctor, you will recall, I hope, your attention being drawn as well by Miss Symes last Thursday to the specific readings which resulted on the assay of the antemortem sample taken from Kevin Pacsai. In that regard, you will recall that the sample, the antemortem sample was first assayed neat and the result was over the maximum which was measurable by the process and it was greater than 5, do you recall that?

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A. The antemortem sample?

17

Q. Yes.

18

A. Yes.

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Q. That was the first assay?

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A. Yes.

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Q. The computer however in respect of that assay you will recall appears to have extrapolated the number of 16 with respect to that assay result; do you recall that?

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A. There was an entry in the book

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2 that appeared to be 16, which I suggested might
3 have been put there due to an extrapolation.

4 Q. As I understood your evidence ---

5 A. I am sorry that was the neat
6 answer, wasn't it?

7 Q. Yes. I would like to be
8 very clear, Doctor, I am talking about the first
9 assay on that sample which was done neat and the
10 recorded result in the digoxin book is greater than
11 5, and the number 16 also appears beside the entry;
are you with me?

12 A. Yes.

13 Q. As I understood your evidence
14 this morning, Doctor, you indicated that you thought
15 that could be a number extrapolated by the computer,
16 but I took from your answer that you were not certain
that that was the case.

17 A. No, it's not certain.

18 Q. If it was not a number
19 extrapolated by the computer, Doctor, can you help
20 us as to where that number would have come from?

21 A. Not really, no question I take
22 it ---

23 It was not reported, isn't
24 that the case, it was not further reported that
25 number?



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Q. That's right, Doctor. I take it, Doctor, that a technician in your laboratory might have been actually performing that assay under your supervision, would not in the absence of some assistance from the computer be able to approximate the actual level of any particular assay?

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A. Yes.

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Q. Is that correct?

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A. That is correct.

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Q. So it is likely that if that number relates to that assay it was a computer produced number?

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A. It is possible, yes.

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Q. I am asking you if it is likely in those circumstances?

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A. It is likely in those circumstances, as I think I indicated. I did show that number to the technologists that could well have written that and he wasn't quite sure whether it was 16 or 10.

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Q. My only point to you, Doctor, is that number I take it would not simply be created by a technician in your laboratory, there would be some basis for its being noted in the book at all?



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A. There could well have been. I didn't write that number as far as I am aware.

Q. Yes. And you have told us in evidence that in your opinion that number, the number of 16 if it does relate to a computer extrapolation of the result of that assay is completely unreliable?

A. Yes.

Q. Do I have that correctly?

A. That is correct.

Q. And I take it, Doctor, that your opinion in that regard is based on the fact that the range of accuracy of the machine or the assay itself beyond 5 is highly suspect?

A. Yes.

Q. All right. Indeed, if the machine could measure with any degree of certainty or reliability beyond 5 nanograms I take it the machine would be calibrated to do so and you would reflect your results accordingly?

A. Yes, that would be reasonable.

Q. And then Doctor, you will recall an antemortem sample, the same sample was assayed again, this time on a times 2 dilution and the reported result was greater than 10. You will recall that from your discussions this morning?



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A. Yes, the final result that we reported was greater than 10.

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Q. And, once again, a number appears by virtue of a handwritten entry in the digoxin book and that number is 10.6 and, as I understood your evidence to Miss Symes last Thursday, you were not sure whether the number that had been extrapolated by the computer was in fact 10.6 or rather whether it was 5.3 which, if multiplied by the number of dilutions involved would result in a number 10.6. You weren't certain which number the computer had produced?

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A. I was not, no.

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Q. All right. Doctor, since testifying last Thursday as requested by Miss Symes, have you had an opportunity to inquire into the matter further and to determine which number in fact was extrapolated by the computer if any?

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A. Yes, I have. I did ask the technologist who was responsible for that batch and he wasn't quite clear either when I pointed out to him this question that had been raised. He was quite confident about the greater than 10 result that had been produced but not what that little notation meant.

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Q. All right. I take it, Doctor, there was no printout still remaining that was



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available to you to which you could look to determine
what that 10.6 number meant?

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A. There was not in our laboratory
in relation to this run.

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Q. All right. Doctor, with respect
to that 10.6 number then, I take it that we are not
really any further ahead today in knowing whether the
computer extrapolation of the result was in fact 10.6
or, conversely, whether it was 5.3. We still don't
know which it was?

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A. No, unless we can locate the
printout.

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Q. All right. I assume, Doctor,
that if subsequently you do you will make that
available to us through your counsel?

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A. Yes. It may just be available -
the police may just have that printout, I'm not quite
clear on that point.

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Q. All right, we will make inquiries
in that regard, Doctor.

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A. All right.

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Q. But with respect to the
possibility that the computer's extrapolated number
was 10.6, I take it we can agree that if that number
is in fact the number that was extrapolated by the

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BB.4

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computer, the computer was then suggesting that the result was really 10.6 times a dilution factor of 2, which would result in a reading of some 21.2 nanograms?

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A. If that was the number extrapolated by the computer, yes.

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Q All right. Doctor, let's deal with the situation or at least the possibility that the number extrapolated by the computer was 5.3.

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A. Yes.

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Q I take it that there is a possibility that the number in fact doesn't reflect a computer extrapolation at all, does it?

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A. That is possible, yes.

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Q All right. But assuming that it does, and assuming that the number that was actually extrapolated was 5.3, as I understood your evidence to Ms. Symes last Thursday, you indicated that it was likely that that extrapolated number, the 5.3, was likely more accurate than the number that had been extrapolated on the first assay, that is, the number of 16 and your basis for saying that, as I understood your evidence, was that the 5.3 was closer to the maximum which the process can in fact measure?

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A. Yes.



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Q. It is closer to the standard
of 5?

A. Yes.

Q. Do I have that correctly?

A. Yes.

Q. All right. That suggests to me,
Doctor, that in your view you were saying that the
probability of accuracy on the assay process
deteriorates the further away one moves from the
maximum standard, i.e., the further away from 5?

A. That's a fair approximation, yes.

Q. Is that what you are suggesting?

A. Yes.

Q. All right. And then if that be
the case, Doctor, if there is then what I would
describe as a continuum of deterioration or decay in
the reliability of the results, as you move away from
5, I suggest to you that what we must be concerned
with is to determine how reliable that reading of
5.3 is in probability terms. Would you agree with
that?

A. In probability terms.

Q. All right. Well, perhaps I can
put the question to you this way, Doctor. You have
said that the 5.3 being closer to the maximum standard



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of 5 is likely more reliable than an extrapolated
number of 16?

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A. Yes.

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A. The 5.3?

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Q. Yes.

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A. I cannot say that with certainty.

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I can only refer you to some of the 5.1's, perhaps
Kevin Pacsai autopsy sample, 5.1, and subsequently
repeated on a different dilution and giving an
approximately similar result.

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Q. All right. Well, I will come
to the other Pacsai runs in a moment, Doctor.

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A. All right.

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Q. My concern is this. When that
number was produced, if it was by the computer, to
your knowledge were any tests undertaken in your
laboratory to determine in statistical terms what
the probability of accuracy was of that number?

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A. No.

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Q All right. And in the absence of those kinds of studies in a statistical sense, can you say in any way how probably accurate that figure is?

A. Not in a statistical way, no.

Q All right, Doctor. And in respect of the confidence range under which you did operate, as I understood your evidence, you indicated that if the machine results in a reading on any given assay of between zero and 5 nanograms you can say with a number of that kind with 95 per cent confidence that the number is accurate given two standard deviations. Do I have that correctly? Give or take two standard deviations, that is the number the machine can measure with accuracy?

A. We would obviously have much more confidence if the number were within our standard curve.

Q All right. And to be within your standard curve it has to be a number between zero and 5?

A. Yes.

Q All right. And if it is a number between zero and 5, you can approach that with a 95 per cent confidence range bearing in mind the number of standard deviations?



BB.8

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A. We would report it.

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Q. All right. And you would do so on the basis of knowing that it was measurable within the range that you felt could be measured with confidence by the machine?

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A. Yes.

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Q. All right. Doctor, my question to you is this. With respect to that number of 5.3 that is recorded in the digoxin book, were any studies done or tests of any kind undertaken in your laboratory to determine what ---

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THE COMMISSIONER: I'm sorry, I'm sorry. The 5.3 was not reported in the digoxin books?

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MS. CRONK: It is in a handwritten entry, sir.

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THE WITNESS: 10.6 is reported, isn't it?

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MS. CRONK: The result that was reported is greater than 10, sir, but the 5.3 is the computer extrapolation.

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THE COMMISSIONER: I'm sorry, 10.6.

MS. CRONK: Oh, I'm sorry.

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THE WITNESS: 10.6.

MS. CRONK: I'm sorry, sir. The question should be directed to the 10.6.

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Q. With respect to that number,



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Doctor, were any studies or any tests undertaken in your laboratory of which you are aware to determine what the number of standard deviations would be with a reading of that kind?

A. No, there was no further sample for analysis.

Q. All right. I take it then, Doctor, with respect to that number you can't help us as to the number of standard deviations that would apply when a result is that far off the standard, nor as to what the value of the standard deviations might be?

A. No.

Q. All right. Thank you, Doctor.

Would it be fair to say in light of that, Doctor, that you would no more rely on an extrapolation of 5.3 as being a reliable and accurate result than you would on an extrapolation of any other number beyond the maximum standard of 5?

A. This is very subjective. I think I indicated previously this morning that if a 5.1 had been obtained I would regard that with greater certainty than a result of 10.9.

Q. All right.

A. Obtained by the computer.



BB.10

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Q. Notwithstanding that no information would be available to you based on what is done in your own laboratory to determine what the probability of accuracy is of a result of that kind?

A. Notwithstanding the statistical considerations that you have just broached.

Q. All right. Thank you, Doctor.

Doctor, with respect to the Pacsai postmortem level, because you referred to the Pacsai readings a few moments ago, do you recall that the postmortem sample was also assayed a number of times. You may recall this without looking at the exhibit book.

A. Yes.

Q. But the first time the sample was assayed it was assayed neat. Do you recall that?

A. Yes.

Q. And the reading was off the maximum?

A. Yes, no result appears in the book.

Q. That's right, and we are talking about the postmortem sample?

A. Yes.

Q. Once again, Doctor we see a handwritten entry and it is APP.14.3 that appears beside that assay.



BB.11

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A. Yes.

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Q. As I understood your previous

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evidence you suggested that that number as well might

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have been a computer extrapolation regarding what the

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actual result was?

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A. Yes.

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Q. Do you recall that, Doctor?

9

A. Yes.

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Q. All right. And as an illustration

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of your suggestion that computer extrapolated numbers

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are not reliable and are not accurate, I take it we

13

can agree, because we know the real level in the

14

Pacsai post mortem case on further dilution was

15

26 nanograms, that that extrapolated number of 14.3

16

is an example of the kind of concern that you would

have about treating a computer extrapolated number

as being reliable?

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A. Yes, the 14.3 is way away from

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5.1.

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Q. All right. And indeed the final

20

measurement of the digoxin reading was 26?

21

A. Yes.

22

Q. Yet the computer seems to have

thrown up 14.3?

23

A. That's right.

24

25



BB.12

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Q. And it did so on a neat assay?

3

A. Yes.

4

Q. All right, notwithstanding that
on the Pacsai antemortem sample it threw up 16?

5

A. Well, whatever it threw up.

6

Q. All right.

7

A. Yes.

8

Q. Then Doctor, finally again with
respect to the Pacsai antemortem level, as I understood
our discussion and then your discussions this morning,
you told me that at the time the greater than 10 level
was made known to you, you had a number of concerns;
the first was that fewer tubes than normal were used
to conduct the assay itself?

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A. Yes.

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Q. Do I have that correctly?

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A. Yes.

4

Q. And the second concern

5

that you indicated that you had at the time was that
the sample itself came in an a CBC tube and you

6

therefore had a discussion with Dr. Costigan about

7

the possible indications of an effect by EDTA, and

8

you tested for that?

9

A. Yes.

10

Q. Right.

11

A. Later.

12

Q. And that as a result of

13

the test you conducted you ruled that out as a
potential explanation, if you will, for that level?

14

A. Yes. We thought it

15

unlikely.

16

Q. All right. And as I

17

understood your evidence this morning, doctor, you

18

indicated a third concern of which I was previously

19

unaware, and that was that it was possible that

20

something happened to the sample itself in the

21

Hematology Department at the Hospital. Did I under-
stand your exchange correctly?

22

A. In respect to this

23

morning, yes.

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Q. Doctor, at the time that that result was made known to you did you make any enquiries of anyone in the Hematology Department to determine whether or not something had been done to the sample which in your view could have coloured the results of the assay?

A. No. I have no reason right now to believe that anything was done to it. I am just saying because of the circuitous route that that sample took before we eventually analyzed it that is a possible concern.

Q. All right. But I take it at the time, doctor, you did not make enquiries in that regard?

A. No.

Q. And I take it that was not a matter that was raised as a concern to Dr. Costigan when you discussed that sample with him?

A. No. No.

MS. CRONK: Thank you, doctor. Those are all my questions. Thank you for your patience.

THE COMMISSIONER: Thank you, Dr. Ellis.

--- witness withdraws.



CC3

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MS. CRONK: Mr. Commissioner, I have made arrangements with counsel for the Hospital that Dr. Soldin will be here I understand in approximately five minutes at a quarter to three.

THE COMMISSIONER: All right.

MS. CRONK: As we have completed a little bit earlier --

THE COMMISSIONER: All right. We will take as long as -- well, will you let me know when he arrives?

MS. CRONK: I will, sir.

--- recess.

--- on resuming.

MS. CRONK: Our next witness, Mr. Commissioner, is Dr. Steven Soldin.

STEVEN JOHN SOLDIN, Recalled
DIRECT EXAMINATION BY MS. CRONK:

Q. Dr. Soldin, you have testified before in these proceedings and I am sure you are aware that you are still under oath.

Dr. Soldin, just perhaps to refresh my memory as well as that of others with respect to some of your previous evidence, we have heard that you are an Associate Biochemist in the Service Division of the Biochemistry Department at



1
CC4 2 The Hospital for Sick Children.
3 A. Right.
4 Q. And you are as well,
5 as I recall your previous evidence, Director of
6 the Therapeutic Drug Monitoring Program at the
7 Hospital.
8 A. Right.
9 Q. And that program you have
10 told us previously was formally introduced in the
11 Hospital in mid-October 1981.
12 A. Correct.
13 Q. Do I have that correctly?
14 A. Yes.
15 Q. And as I recall your
16 previous evidence as well, doctor, you told us that
17 during the period July 1980 to March of 1981 your
18 laboratory was not involved in the conducting of
19 digoxin assays at the Hospital. Do I have that
20 correctly?
21 A. That is right.
22 Q. All right. It did, how-
23 ever, subsequently become involved but that was not
24 until July of 1981.
25 A. That is correct.
Q. Right. And as well,



1
CC5 2 doctor, you have told us that you, yourself, were
3 not personally involved, leaving aside the question
4 of your laboratory as a unit. You, yourself, were
5 not personally involved in conducting digoxin assays
6 at the Hospital during the period with which we are
7 concerned unless you happened to be the clinical
8 chemist on call on any particular evening or any
particular weekend.

9 Do I have that correctly?

10 A. That is correct, yes.

11 Q. And as a routine matter,
12 doctor, and as I understand it, digoxin assays
13 again during the time period with which we are
14 concerned were not conducted on a routine basis over
the weekend. Do I have that correctly?

15 A. At that time, yes.

16 Q. At that time?

17 A. Yes.

18 Q. All right. Doctor, as
19 I understand it, you were the clinical chemist on
20 call on the weekend of March 21, 1981.

21 A. Yes.

22 Q. Is that correct?

23 A. Yes, that is correct.

24 Q. And, doctor, on Saturday,
25

No! Costigan didn't learn of Miller's death until c 7:30 am, Sat Mch 21 when he spoke to the resident who had been at the arrest.

Costigan went to Path^y, asked Taylor to take sample for dip assay.

There is no ev. that Costigan ever dealt directly w. Sordin. And Sordin was summoned to the Hospital in the late afternoon of March 21 at Cowie's behest!



1
CC6 2 March 21, 1981, were you requested to arrange for
3 a digoxin assay to be conducted in respect of a
4 sample taken from the body of a patient known as
5 Allana Miller?

6 A. I was, yes.

7 Q. Can you tell us, doctor,
8 how that came about?

9 A. I can give you my
10 recollection, which is that at two or three in the
11 morning I received a phone call from Dr. Costigan
12 asking me to have a digoxin assay done on a sample
13 from Allana Miller.

14 I mentioned to him I would arrange
15 that and he should let me know when he had a
16 sample. I was given to understand there wasn't a
17 sample at that time. Later in the day a sample
18 did arrive and I arranged for I think it was Candy
19 Cheong to do the analysis.

20 Q. May we stop there just
21 for a moment, doctor.

22 A. Sure.

23 Q. You said that you received
24 a phone call I think you said at two or three o'clock
25 in the morning from Dr. Costigan?

A. Right.

Sat a.m? I'll bet!



1
CC7 2 Q. Was any information pro-
3 vided to you at that time as to whether or not the
4 patient was alive or dead?

5 A. I can't recall absolutely.
6 I think the information given to me was either that
7 the patient had died or that the patient had had
8 an arrest, one or the other. I think, but I can't
be definite about that.

9 Q. Was it your impression
10 at the time then that the sample that was intended
11 to be sent to the laboratory by Dr. Costigan was a
12 post mortem sample? Or did you have any understanding
one way or the other?

13 A. Well, he obviously never
14 had a sample at that point in time. Otherwise I
15 would have called Candy Cheong in at two or three
16 in the morning so a sample was not there I think at
17 that time.

18 Q. Right. And I take it
19 then, doctor, you did subsequently call Candy Cheong,
20 and I take it she is a technician in the laboratory?

21 A. Correct.

22 Q. She then came into the
Hospital to perform the assay?

23 A. Right.

24

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CC8

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Q. Did you as well come into the Hospital after you had received the telephone call from Dr. Costigan?

A. I came in once Candy Cheong had completed the runs, yes, I came in to the Hospital.

Q. After the run had been completed?

A. After the run had been completed.

Q. All right. And, doctor, at the time of speaking to Miss Cheong with respect to the conduct of the assay, did you provide her with any instructions as to what she was to do with the sample?

A. Yes. I asked her to do it in several dilutions and to then report to me as soon as she had the data.

Q. Now, doctor -- I'm sorry, was there something you wanted to add?

A. I think I might have asked her at the same time to do the pharmaceutical preparations to measure the digoxin concentration.

If you give me that book -- is it over here?



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Q. Well, we will come to that in a moment then, doctor, but as best you can recall I take it when you spoke to Miss Cheong you instructed her first to run the sample at various dilutions.

Do I have that correctly?

A. That is correct.

Q. You think as best you can recall it that as well you instructed her to run an assay on a pharmaceutical preparation?

A. Right. Taken from that ward. A digoxin preparation.

Q. Was that then a sample of digoxin per se to be taken from the ward?

A. That is correct.

Q. Did you ask Miss Cheong to arrange to take obtain that sample?

A. Well, either Miss Cheong or the doctors that I had been speaking with, yes.

Q. All right.

A. Now, it was probably the doctors that I had arranged this with who then delivered a sample to Miss Cheong.

Q. Why were you intent that that be done at that time, doctor?

A. Well, one of the possi-

Why not he guess this before the
assay results were known?

Was he aware, in (as he says) the
early hrs of Sat a.m., of the
Pacsaí & Estrella works? — NO

See p. 1281

Basic?



CC10

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bilities is that an error had been made in the
pharmaceutical preparation.

Q. This was --

A. And therefore it would be
wise to measure the concentration of digoxin in that
preparation as well.

Q. Doctor, that is precisely
why I asked the question.

Were you under the impression at
the time you were requested to arrange for the
assay of the sample that there might be a problem
with the reading?

A. I am sure that was my
understanding there may be a problem, there may be
a high reading and I wanted to -- at the same time
because it took at that time three hours to do a
digoxin run, so if you missed out on the pharmaceutical
prep. it would take another three hours to do another
run subsequently.

Q. I see.

A. So I wanted to do them
simultaneously.

Q. Doctor, at the time you
received the phone call from Dr. Costigan requesting
you to arrange for the assay, were you at that
stage aware of the deaths of Kevin Pacsai and Janice



CC11

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Estrella?

A. No. I don't recollect
being aware of the deaths at that time.

Q. I take it then you have
no recollection of being aware at that time of any
digoxin readings which may have been produced at the
Hospital in respect of either of those patients?

A. Not -- no, not of high
digoxin readings with respect to those patients.

Q. All right. Then, doctor,
with respect to the assay itself, I would ask you --

Perhaps, Mr. Registrar, if you
could provide the doctor with a copy of Exhibits
32A and 32B.

Doctor, I would ask you to refer
first to Exhibit 32A.

A. Right.

Q. Turn if you would to
Tab 42.

A. Yes.

Q. Doctor, this volume
represents a number of documents introduced as
exhibits in the preliminary hearing in The Queen vs.
Nelles. The document which appears at Tab 42 is
a clinical chemistry requisition form bearing
No. D57974 with reference specifically to Allana



1
CC12 2 Miller. Do you see that child's name?

3 A. Yes.

4 Q. And, doctor, as well the
5 requisition form bears what appears to be an
6 autopsy number, No. 85/81.

7 A. Yes.

8 Q. Do you see that?

9 A. Yes.

10 Q. It appears to be signed
11 by Dr. Taylor.

12 A. Yes.

13 Q. There is a date stamp
14 that appears on it, doctor. It is March 21, 1981,
15 1434 hours.

16 Would I be correct in interpreting
17 that as meaning that this particular sample was
18 received in the laboratory at approximately 2:34 p.m.
19 on March 21st?

20 A. Right.

21 Q. All right. And there is
22 an indication on the form as well that the specimen
23 is blood and that a digoxin assay has been requested.

24 A. Right.

25 Q. Doctor, I would ask you
now to turn to Exhibit 32B, the other volume of



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bound documents beside you, and to Tab 45, if you would, page 29.

Do you have that, doctor?

A. Yes.

Q. Page 29?

A. Yes.

Q. Doctor, if you look at the right-hand side of the page, under the entries for March 21, 1981, we see a reference to the same sample number that appeared on the clinical chemistry requisition form that we looked at a moment ago, Sample D57974, and that sample appears to have been assayed a number of times on March 21st.

Do I have that correctly?

A. That is correct.

Q. And this appears to be a sample taken by Dr. Taylor as reflected in the requisition form.

A. Yes.

Q. And the sample appears to have been assayed first on a neat basis, and this appears to have been done twice.

A. Right.

Q. And each time the resultant reading was greater than 5.



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A. Right.

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Q. Then it appears to have

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been assayed at a dilution times 2, doctor, and

5

this appears to have been down twice.

6

A. Yes.

7

Q. And each time the resultant

8

reading was greater than 10.

9

A. Correct.

10

Q. And finally, doctor, it

11

appears that it was assayed a fourth and a fifth

12

time, again on dilution. This time times 10. The
reading in each case is expressed to be greater than
50.

13

Do you see that?

14

A. Right.

15

Q. Doctor, we see as well

16

a handwritten entry beside the first dilution of

17

greater than 10 indicating approximately 73, and

18

below the second dilution at times 10 an indication
of approximately 72.

19

Can you tell us what that entries

20

refer to if you know?

21

A. They refer to an estimation
of the digoxin concentration in that sample but
not a direct quantitation. In other words, an

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estimation.

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The standard curve didn't go up to -- it only goes up to 5 and this result would have been 7.2 or 7.3 if one extended that standard curve.

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Q. All right. Would these then have been approximations made by Miss Cheong when she was running the assay or would these have been numbers that we have heard in some cases can be extrapolated by the computer?

11

12

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A. They can be extrapolated by the computer. I can't recall. I think they were extrapolated.

14

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Q. By the computer?

A. Yes.

Q. And, doctor, in the end result, then, I take it that this particular sample was assayed a total of six times with a final result that was known on March 21st being a result of greater than 50 nanograms with an approximation that that level might in fact be 72 or 73?

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A. Correct.

Q. And that I take it was the result of the various assays conducted on this sample on that day?



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A. Right.

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Q. Then, doctor -- well, with respect to the assay results themselves conducted on that day I take it that Miss Cheong then did contact you when the assay runs had been completed?

A. Correct.

Q. Had you ever before, doctor, had experience with a digoxin level reading of greater than 50 on any sample that you had been involved with?

A. At that time, no.

Q. Yes. And as I understand your previous evidence, doctor, you indicated, and this is found, Mr. Commissioner, at Volume 8, page 1252 to page 1253, that in your opinion there is a discernible range of digoxin levels for infants which fall either into the subtherapeutic category, therapeutic category or the possible toxic category.

Do you recall giving evidence in that regard previously?

A. Right.

Q. And as I recall your evidence, doctor, you indicated that the sub-therapeutic range for digoxin for infants is anywhere from zero to .8 nanograms per millilitre. Do



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I have that correctly?

3

A. Right.

4

5

Q. And the therapeutic range
in your opinion would be from between .8 to 2 nano-
grams. Do I have that correctly?

6

A. Correct, yes.

7

8

Q. And the toxic range,
again for infants, would be above .2 nanograms.

9

A. Above 2.

10

Q. Above 2, I'm sorry.

11

12

13

I take it then, doctor, when you
were informed by Miss Cheong that these series of
assays had resulted in a level of greater than 50
that was a matter of some concern to you?

14

A. It was, yes.

15

Q. All right.

16

17

18

19

THE COMMISSIONER: Do I understand --
you said something about the curve. Can you help
me as to why it wasn't diluted further to get an
exact...

20

THE WITNESS: Well, as I mentioned
it took three hours to do a run.

21

THE COMMISSIONER: Yes.

22

23

THE WITNESS: A result of greater
than 50 and an approximation of 72 is -- it could have

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25



1

2 been run again. It could have taken another --

3 THE COMMISSIONER: There was
4 enough --

5 THE WITNESS: There was enough
6 sample to run it again. In fact we ran it again the
7 next day.

8 MS. CRONK: Q. I was just going
9 to say in fairness to you, doctor, I understand, and
10 I will come to the events of March 22nd --

11 THE COMMISSIONER: Oh, yes, yes.

12 MS. CRONK: But as I under-
13 stand it it was assayed again the next day.

14 THE COMMISSIONER: Yes, I saw it.
15 I remember it even.

16 MS. CRONK: Q. Doctor, perhaps
17 you can help us: Was there any particular reason
18 why the sample was not assayed again on the 21st
19 instead of the next day?

20 A. Well, I didn't see an
21 urgent need to do that I guess once we had an
22 approximate result of 72 and we had many assays
23 saying that the result was definitely over 50, I
24 thought we could do that next run at another time.
25



DD/DM/ak

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Q. And Doctor, once you had been contacted by Miss Cheong and informed that these particular assays that were done on the 21st had been completed, did you then when you got to the Hospital take the opportunity to review the methodology that had been used by her to review the results to determine whether or not the assay had been performed correctly?

A. Yes, I did.

Q. And after having done that, Doctor, what conclusion did you reach?

A. I thought the assay had been performed correctly.

Q. Doctor, we see on the same page, page 29 for March the 21st a reference to oral medication, and then what appeared to be the results of four, potentially five assay results. Are these the assays with respect to the pharmaceutical preparation of digoxin that you requested Miss Cheong to run?

A. They are.

Q. Can you explain for us, Doctor, the meaning of the entries which appear beside the words "oral medication", and we see there is a result of (3.7) (4.1) (0.2) and then (0.3). Can you



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- tell us first why those particular results are expressed in brackets in the digoxin book?

A. That is the way Miss Cheong wrote it.

Q. I would have thought that, Doctor, but I suppose in fairness I put the question badly. Is there any particular significance in your mind to the fact that those results are expressed in brackets?

A. No.

Q. And Doctor, after you had been called into the Hospital and you had received the results of the assays from Allana Miller, did you also review the methodology employed by Miss Cheong and the results involved in conducting the assays on this oral medication?

A. I did, yes.

Q. What did those results indicate to you, if anything?

A. The conclusion was the concentration of digoxin and the preparation was more or less what it was stated to be.

Q. Doctor, we have heard that during this particular time frame, that is July of 1980 through to the end of March 1981 digoxin was



1
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3 available in a number of forms in the Hospital, one
4 of which was the elixir form; the second of which was
5 ampules which would either be in adult concentration
6 or pediatric concentration. I take it that the
7 reference to oral medication which appears in the
book is a reference to elixir.

8 A. It is, yes.

9 Q. Can you tell me, Doctor, were
10 any assays done on samples of digoxin ampules from
11 the particular wards involved in these patients at
this time?

12 A. Not that day, no.

13 Q. Can you help me, Doctor, as
14 to why oral medication was chosen as a pharmaceutical
15 sample of choice to be tested as opposed to an
16 ampule of digoxin be it pediatric or adult?

17 A. Again I will have to go back
18 to my recollection of this, this was a long time ago.
19 I am sure we had discussions with the clinicians
20 involved and they must have indicated that this
21 patient was on that medication, and so we checked
the source.

22 Q. And I take it, Doctor, that
23 from what you have said that to the best of your
24 knowledge the sample of the elixir which was then
25



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3 assayed came directly from the ward where Allana
4 Miller had died?

5 A. Right.

6 Q. And in respect of the testing
7 of the ampules, do I take your answer a few moments
8 ago to mean that subsequently an ampule of pediatric
9 or adult concentration of digoxin was tested on
10 assay to determine the accuracy of the concentration
11 contained in those ampules?

12 A. Not by myself, I was on call
13 only for the weekend, Dr. Ellis may or may not have
14 had time.

15 Q. You didn't undertake to
16 instruct others to take any further assays on these
17 forms of digoxin?

18 A. No.

19 THE COMMISSIONER: Were you saying
20 you had information of it having been done later?

21 THE WITNESS: No, I have no
22 information.

23 MS. CRONK: Q. Doctor, when I asked
24 you what the results that were obtained on the sample
25 of elixir suggested to you, as I understood your
answer you indicated that it appeared that the
concentration of digoxin contained in the sample was



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as stated by the pharmaceutical company?

3

A. That is correct.

4

Q. I take it then, Doctor, that

5

you had no further concern at that stage with the

6

actual supply of elixir that was tested might have

7

contained an elevated concentration over what would

8

be expected given the indications from the pharmaceu-
tical company?

9

A. No.

10

Q. And Doctor, that appears to

11

have been tested in a number of dilutions, and

12

simply so the record is clear, am I reading the

13

entries correctly, that you did this first with the

14

dilution of 10,000?

15

A. Right.

16

Q. And then again at 10,000?

17

A. Yes.

18

Q. I am having difficulty with
the next one, Doctor.

19

A. That would be the dilution of

20

100,000.

21

Q. Does that appear to have been

22

10,000 that was repeated again?

23

A. No, 100,000 was repeated twice

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and then 10,000.

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Q. Do I take it then that there were four assays conducted two at a dilution of 10,000 and two at a dilution of 100,000 each?

A. Right.

Q. Doctor, after you had checked both the results and the methodology in respect of the actual sample from Allana Miller, and the sample of digoxin elixir on which the assays had been run on the 21st, what then did you do knowing the results on the samples from Allana Miller?

A. Well, Dr. Costigan was standing very close to me so I related the information to him. I then phoned several people and gave them this information.

- - -



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Q. To whom did you report the results at that stage, Doctor?

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A. Dr. MacLeod was one, Dr. Carver was another, and Dr. Goldberg was another. I am not clear exactly when I reported that result to Dr. Goldberg, but it was in that time.

8

9

Q. And you have said, I thought you said that Dr. Costigan was standing near to you?

10

11

A. He was, yes.

12

13

Q. Was he in the lab at the time you were checking these results?

A. I may have called for him on the intercom.

14

15

16

Q. And with respect to your call to Dr. Carver, had it been suggested to you by Dr. Costigan or anyone else you should report these results directly to Dr. Carver?

17

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A. No, I just felt that these results were very significant and I should report it to him, he is head of the Clinical Pharmacology and I should report it to the Medical Director and Biochemistry Chief and I tried to do that.

22

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Q. Doctor, do you remember what time of day on the 21st of March those assays were completed?



DD2
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A. I am sorry, could you repeat
that for me?

4

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Q. Do you remember what time of day
on Saturday, March 21st, those assays were completed?

6

A. It was close to 7:30 in the
evening if I recollect.

7

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Q. And I take it that on the basis
of the information, recognizing that a further dilution,
a further assay was conducted the next day, that on
the basis of the information available to you at
approximately 7:30 that evening you would report to
those individuals with whom you discussed it that a
number of assays had been conducted, that the final
results indicated the level was greater than 50, and
that there was an approximate value of 72 or 73?

15

A. That is correct.

16

17

Q. Do you recall relating that
information to those three individuals whom you called?

18

A. I did, yes.

19

20

THE COMMISSIONER: May I just
interrupt, I want to go back to page 29 of the
bracketed figures. What are they supposed to represent?

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22

THE WITNESS: The concentration of
nanograms per millilitre.

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THE COMMISSIONER: What is the



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concentration supposed to be, this is the medicine,
isn't it?

THE WITNESS: That is correct.

THE COMMISSIONER: I always thought
the concentration was, it was digoxin, wasn't it?

THE WITNESS: Yes, digoxin in the
medicine but that is after carrying out the dilution
of 10,000.

THE COMMISSIONER: Oh, I see. Well,
when you have an ampule or an elixir of digoxin do
you not have digoxin, I would have thought a
concentration - I just don't understand this at all.
You have a medicine, digoxin, which was in a form in
a pure form, is it not?

THE WITNESS: This was in a syrup, yes.

THE COMMISSIONER: I am sorry, in a
syrup?

THE WITNESS: Yes.

THE COMMISSIONER: Is that the way it
is fed to the child?

THE WITNESS: That is one form.

THE COMMISSIONER: And that is the
concentration; how do these figures compare to the
concentration you are supposed to have?

THE WITNESS: Well, the concentration



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was supposed to be, ideally would have a result of 5.

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THE COMMISSIONER: So this would be

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lower?

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THE WITNESS: This was somewhat lower,
yes.

6

7

THE COMMISSIONER: A concentration of
5, 3.7 and 4.1 are somewhat lower, what are these
figures of 0.2 and 0.3?

8

9

THE WITNESS: That was an extra
dilution.

10

11

THE COMMISSIONER: That is diluting
it another ---

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THE WITNESS: Another tenfold and the
assay uses all sorts of accuracy and precision, as you
know.

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THE COMMISSIONER: So that would be,
the 0.2 would presumably be 2 and the 0.3 would be 3,
is that it?

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MS. CRONK: Q. Well, Doctor, those
two low results were achieved in a dilution of 100,000,
is that correct?

20

21

A. Right.

22

23

Q. Do you recall the quantity of
the sample that was provided, the quantity of the
sample of elixir that was used for those assays?

24

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DD2
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A. The whole bottle.

3

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Q. And how much of that would have been used, do you know by Miss Cheong for the purposes of running those assays?

5

6

A. An extremely small quantity.

7

8

Q. Was there then an expectation in your mind that the results should have been 5 nanograms or greater than 5?

9

10

11

A. The result should have been as are reported 5 nanograms after carrying out the dilution.

12

13

Q. And was that because, Doctor, that was what you anticipated the actual concentration to be in the sample that was tested?

14

15

A. As tested by the manufacturer, yes.

16

17

18

19

Q. So that the sample that you received bore some indication from the manufacturer that the concentration was the equivalent of 5 nanograms?

20

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A. Yes.

Q. Thank you, Doctor. You have told us after checking the results both of the assays that had been run on the elixir sample and the assays that had been run on the Allana Miller sample, that

Was there another?



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you then contacted various people in the Hospital and reported the results that were then available to you. Did it occur to you, Doctor, that given a level of greater than 50 nanograms, which would approximate to be 72 or 73, that the death of this child could have been attributable to digoxin intoxication?

A. Yes, that was one possibility.

Q. I take it, Doctor, that the following day this sample was assayed again. Now, would you turn if you would to page 30 of your digoxin book, and we see there the entries for Sunday, March 22nd, 1981.

A. Yes.

Q. And if we look down at Item No. 7 in that list we see that the same Sample No. D57974 was again assayed but this time in a dilution of 20, is that correct?

A. Correct.

Q. And the results of that further dilution on assay was 78 nanograms, do I have that correctly?

A. Yes.

Q. Doctor, there appears, there is a check mark which appears beside the dilution figure



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of 20, can you help me as to what that means? Do you know?

A. I don't.

Q. And Doctor, with respect to the sample and the assay that was performed again on Sunday, March 22nd, were you personally in the laboratory at the time that sample was re-assayed?

A. Shortly thereafter.

Q. Was the assay then conducted under your supervision by a technician in your laboratory?

A. It was, yes.

Q. Was it Mrs. Cheong again?

A. No, it wasn't.

Q. After the assay had been completed and the result was available of 78 nanograms, I take it the result was drawn to your attention?

A. It was.

Q. And did you at that point, Doctor, again take the opportunity to check the methodology that had been used on that assay, together with the results, to determine whether or not that assay had been conducted properly?

A. I did.

Q. And what conclusion or view did



DD2

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you reach after having conducted that review?

3

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A. That the assay had been appropriately performed.

5

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Q Did you then at that point, Doctor, on the basis of reviewing the results and reviewing the methodology, both from the previous day and from Sunday's assay on March the 22nd, formulate an opinion as to whether or not the level of 78 nanograms that had resulted was valid or invalid?

10

11

A. Valid I guess as evaluated by this technique, this assay technique.

12

13

14

15

Q I take it, Doctor, you had no concern in your mind at that time that there was a problem with the assay itself in respect of any of those assays that had been conducted on this sample?

16

17

18

19

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A. I think that is not quite right. One always is concerned as to the possibility of error, and I was concerned at that time as well, but nevertheless with the knowledge that I had at that moment I thought this was an extremely high reading of digoxin and there was no other explanation for it.

21

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24

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Q On the basis of the review that you had conducted, Doctor, did anything present itself to you either in the way in which the assay had been conducted or in the record of the results themselves



DD2
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that suggested that that level of 78 was erroneous?

3

A. No.

4

Q. Doctor, were you aware at the

5

time that these assays were being run on the Saturday,

6

March 21st, that a meeting had been held that afternoon

7

at the Coroner's offices to discuss the deaths of

8

Kevin Pacsai and Janice Estrella?

9

A. No, I was not aware of it.

10

Q. To the best of your knowledge,

11

Doctor, other than the sample that was assayed and

12

tested on Saturday and then on Sunday, the sample we

13

have just looked at, were any other digoxin assays

14

conducted in respect of specimens from Allan Miller,

conducted at the Hospital to the best of your knowledge?

15

I am sorry, I put the question badly.

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Doctor, we know that these assays on this sample were conducted on the Saturday and the Sunday under your supervision in the laboratory?

A. Right.

Q. All right. To the best of your knowledge were any further digoxin assays conducted in the Hospital after March 22nd in respect of samples from Allana Miller?

A. Not to my knowledge, no.

Q. Doctor, I would ask you to turn if you would again to Exhibit 32A as one of the bound volumes before you, Tab 43 of that book.

A. All right.

Q. Do you have that, Doctor?

A. Yes.

Q. All right. Doctor, we see there yet another clinical chemistry requisition form. This one relates to Sample No. D57964 and once again it bears the name of Allana Miller. Do you see that?

A. That's right.

Q. On the top right-hand side of the page, Doctor.

A. Right.

Q. Once again, Doctor, it appears to bear the signature of Dr. Taylor only this



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time there is a reference on the left-hand side of the page of a request for a digoxin assay and a reference below that to "eyes". Do you see that?

A. Yes.

Q. All right. And once again from the date and time stamp, Doctor, it appears that this requisition form and the sample to which it related were received at the laboratory on March 21, 1981 again at approximately 2:34 in the afternoon.

A. Right.

Q. Is that correct, Doctor?

A. Right.

Q. Doctor, do you have any recollection of a sample from Allana Miller, be it eye fluid or eye tissue having been received in the laboratory during the afternoon of March 21st?

A. No, I don't.

Q. All right. Doctor, do you know or have any knowledge concerning whether or not a digoxin assay was conducted in respect of this sample at the Hospital?

A. Not to my knowledge.

Q. All right. Do you know what happened to the sample?

A. No, I don't.



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Q. All right. Can you, and

3

perhaps you can't, Doctor, I suspect that you can't,

4

but can you help us as to whether it was eye fluid

5

or whether it was eye tissue or do you know?

6

A. I don't know. Presumably eye
fluid but it doesn't say that.

7

Q. All right. Doctor, did you have

8

then any knowledge at all that a specimen, be it

9

eye fluid or eye tissue had been received or taken

10

in respect of Allana Miller and sent to the laboratory

11

at any stage at the Hospital?

12

A. I had no knowledge at that
time.

13

Q. All right, thank you, Doctor.

14

Doctor, as I recall your previous
evidence you indicated that the interpretation of
assay results is very often impossible unless the
sample which is assayed is taken at the right time
after the last dose of the drug is given. Do you
recall that evidence?

15

16

A. Yes.

17

18

Q. Were you concerned in the case
of Allana Miller once these results were made known
to you to determine when the sample had been taken in
relation to the last dose of digoxin that had been

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administered?

A. Yes, I was.

Q. Did you make enquiries in
that regard?

A. I'm sure I did.

Q. Doctor, we know in respect of
Allana Miller at least from the contents of the medical
record, it appears that the last dose of digoxin was
administered to her at 9 o'clock during the evening
of March 20th, the evening before her death?

A. Right.

Q. If that be so and the sample
was taken at autopsy because the requisition form
bears the signature of Dr. Taylor, would you in
those circumstances have any concern that this sample
was taken too close in point of time to the time at
which the last dose of digoxin was administered?

A. What was the recorded time of
death again?

Q. All right, according to the
progress notes in the medical record, Doctor, the
child died at approximately 3:30 a.m.

A. Yes.

Q. In the early hours of March
21st.



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2

A. Yes.

3

Q. All right, to repeat my

4

question. In those circumstances if the sample was
5 taken as the medical record -I ask you to accept from
6 me that it suggests that it was given at 9 o'clock
7 on March 20th, the child died at 3:30 a.m. and the
8 sample appears then to have been taken at autopsy,
9 in those circumstances would you have any concern
10 that that sample was taken in too close a proximity
to the time at which the last dose was administered?

11

A. No.

12

Q. All right. Doctor, you have

13

told us of the concerns that you investigated, if
14 you will, concerning the actual conduct of the assay
at the time these results came out. You have also
15 told us of your concern that a sample of the digoxin
16 elixir be assayed to determined whether the
17 appropriate quantity was in fact provided as suggested
18 by the manufacturer, were you at the time of being
19 made aware of the end result on the Miller sample,
20 the level of 78, concerned that there might be another
21 explanation as to why that level could have resulted
22 in this child. Were there any other possible
explanations that occurred to you at that time?

23

A. Well, there are several I guess.

24

25



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2 One would be that digoxin had been administered to
3 this patient consciously in an excessive amount;
4 another would be that it had been administered
5 inadvertently in an excessive amount; a third would
6 be a problem with the timing relative to the dose or
7 was the sampling taken from a site which was
8 contaminated with digoxin; a fourth possibility
9 would be that there is indeed a problem with the
analytical procedure.

10 Q. All right. Doctor, you have
11 given us a number of reasons. If I can deal with
12 the last first, a problem with the analytical
13 procedure. I take it that you did enquire into that
14 matter by reviewing the methodology and the results
15 that had been obtained and from your previous answers
16 I take it you satisfied yourself that there did not
17 appear to be an analytical problem with the assay
itself. Do I have that correctly?

18 A. Well, not quite, no.
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Q. All right.

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A. One can evaluate certain things

4

when one checks over a particular assay, that the

5

quality controls perform as expected, but there are

6

a number of things that one cannot evaluate that

7

quickly and, that is, how specific is this assay,

8

for example, what other compounds might interfere

9

with the assay and give rise to a supposed digoxin

10

concentration of 78 nanograms per millilitre.

11

So that there are things that one cannot

12

check out very readily. There are other things

13

that one can evaluate very quickly. So, I was happy

14

with the way the technologist had performed the

15

analytical procedure. I couldn't answer whether or

16

not the assay was a ---

17

Q. I understand, Doctor.

18

A. Yes.

19

Q. I understand. I take it as

20

part of the review that you conducted you did check

21

the controls that were being used during the course

22

of those assays?

23

A. Yes, I did.

24

Q. All right, and based on that

25

review was there any problem that presented itself

to you with respect to the controls?



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A. No, no problem.

3

4

Q. All right. Doctor, you have told us of a second possible explanation and, that is, a concern with respect to the timing of the sample.

5

6

A. Yes.

7

8

Q. You told us that you made enquiries in that regard and I take it on the basis of the information that was provided to you that was not a concern?

9

10

A. Right.

11

12

Q. All right. You mentioned as well, Doctor, that the site from which the sample had been taken was of relevance that the site may have been not specifically in this case, but a site may be contaminated and thus affect the digoxin assay result?

13

14

15

16

A. Right.

17

18

Q. In respect of Allana Miller, were you aware of the circumstances under which this sample had been taken at autopsy?

19

20

A. No, I had no check on that.

21

Q. All right, so, that was a possibility?

22

23

A. That was a possibility.

24

Q. That you were unable to rule

25



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2

out at that stage?

3

A. Unable to rule out, right.

4

Q. All right. Thank you, Doctor.

5

I take it obviously the possible explanation of

6

either deliberate or accidental administration of

7

the drug was not a possibility that you could check

8

out at that stage?

9

A. Right.

10

Q. All right. Doctor, with respect

11

to situations where a sample of digoxin is in fact -

12

I'm sorry, where a sample from a patient for digoxin

13

assay is in fact taken too close in point of time

14

to the time of the administration of the last dose,

15

I take it in those situations elevated digoxin

16

results may occur?

17

A. Yes.

18

Q. All right. I take it, Doctor,

19

that in the course of your experience in the

20

Hospital in running digoxin assays you have encountered

21

situations of that kind?

22

A. Correct.

23

Q. All right. In that kind of a

24

situation, Doctor, have you ever had experience with

25

a digoxin level of greater than 50 resulting from

26

that set of circumstances?

27

28

Is he referring to Estrella or
have there been other such cases?



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A. Not if timing is the only problem involved here. We have had experience of concentrations over 50 when there was contamination of the sample.

Q. All right. I was directing my attention for the moment to the issue of the timing at which the sample was taken. I take it that that would be an unusual event to see a level of that high for that reason?

A. Right.

Q. All right, thank you, Doctor.

THE COMMISSIONER: I'm sure we have had this before but what would the level that was taken immediately, a therapeutic dose, an ordinary therapeutic dose, if they took it immediately afterwards, say, within the first hour - I'm sure we have had all of this before. In fact, I think we have had charts on it, haven't we?

MS. CRONK: Yes, we have, sir.

THE WITNESS: I'm sure you have.

THE COMMISSIONER: It may not be in your...

THE WITNESS: It will vary. No, I think a clinical pharmacologist will address it more readily.



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2EE5

THE COMMISSIONER: All right.

3

MS. CRONK: Q. Based on your own

4

experience, Doctor, and we will have extensive

5

evidence from clinical pharmacologists in that

6

respect, but based on your own experience with what

7

I take to be numerous digoxin assays - am I correct?

8

A. Right.

9

Q. Have you ever seen a level

10

greater than 10 that has resulted purely as a

11

function of the time at which the sample was taken?

12

A. If you are saying greater

13

than 10 I think I would say yes; if you say greater

14

than 20 I would hesitate.

15

Q. All right, thank you Doctor.

16

Doctor, with respect to this final

17

assay that was done on this sample on Sunday, March

18

22nd when the result of 78 nanograms was ultimately

19

produced, you had had the prior evening you have

20

told us a number of discussions with a number of

21

people in the Hospital to whom you felt the level

22

should be reported that evening. Did you then on

23

the Sunday when that final assay result was available

24

report it to others in the Hospital as well?

25

A. I did, yes.

Q. All right. And to whom did you



2EE6

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2

report that result on the Sunday?

3

A. Well, to the same individuals,

4

essentially.

5

Q. Dr. MacLeod?

6

A. Dr. MacLeod.

7

Q. Dr. Carver?

8

A. Dr. Carver and Dr. Goldberg and

I think Dr. Hill.

9

Q. And Dr. Costigan or no?

10

A. Or Dr. Mounstephen. I'm not

11

sure, it was one or the other.

12

Q. Do you recall, Doctor, when

13

on Sunday, March 22nd that assay on Allana Miller

14

sample had been completed, when those results were

15

available?

16

A. It was around noon.

17

Q. All right.

18

A. I'm not sure.

19

Q. And was it immediately or

shortly thereafter that you reported those results

20

to the individuals you have just outlined?

21

A. It was, yes.

22

MS. CRONK: Thank you. Mr. Commissioner,

23

I am about to move into the samples conducted on

24

Justin Cook.

25



ANGUS, STONEHOUSE & CO. LTD.
TORONTO, ONTARIO

Soldin, dr.ex.
(Cronk)

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THE COMMISSIONER: We will take
15 minutes then.
---Short recess.



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---On resuming.

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THE COMMISSIONER: Yes, Miss Cronk.

4

MS. CRONK: Thank you, Mr. Commissioner.

5

Q. Doctor, as I understand it in

6

addition to the reassaying of the Allana Miller

7

sample on Sunday, March 22nd, you also had occasion

8

to supervise a number of digoxin assays in respect

9

of samples from Justin Cook. Is that correct?

10

A. Right.

11

Q. Can you tell me, Doctor, first
how that came about?

12

A. I received another phone call;

13

this time I think it was close to 5:00 a.m. that

14

there had been another death in the cardiac ward

15

that needed a stat assay for digoxin, and I phoned

16

to the laboratory and none of Dr. Ellis' technologists

17

was actually working on the midnight shift so he

18

was there at the time, and I asked him to do that
assay.

19

Q. Doctor, who did you receive

20

that phone call from to the best of your recollection?

21

A. Dr. Mounstephen. The second

22

one?

23

Q. Yes.

24

A. Was I think Dr. Mounstephen.

25

/EMT/ak



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Q. You have told us you think that was approximately 5:00 a.m. That would be 5:00 a.m. in the morning of Sunday, March 22nd?

A. Yes.

Q. When you reached the technician working in Dr. Ellis' laboratory did you then personally come into the Hospital?

A. I did, yes.

Q. You did not then in this case wait for the results of the assays to be completed?

A. No, no, the same as --

Q. No, all right. Thank you, Doctor.

Did you in speaking to the technician by telephone provide the instructions as to how the assay was to be performed?

A. I did, yes.

Q. What did you instruct the technician to do?

A. You mean check on --

Q. To help you, Doctor, the results of the assay appear to be set out at page 30, of Exhibit 32B. If you will turn to Tab 45, page 30. We see on the left hand side of the page, Doctor, page 30, what I take to be the results of the various



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assays that were conducted initially on Sunday,
March 22nd, and having those results in front of
you (and I will come back to the particular assays
in a moment) (but do those entries on page 30 help
you to refresh your recollection as to what
instructions if any you gave to the technician when
you called in to the Hospital?

A. Yes. I think I must have told
Mladen - he was the technologist involved - to perform
the assay in dilutions of 2 and 10 and 20.

Q. Yes.

A. On Justin Cook. I at the same
time asked him to repeat the Allana Miller sample
in a dilution of 20.

Q. All right. Dealing with
Allana Miller sample for the moment why were you
interested in having that sample reassayed at that
time?

A. Well, we didn't have a quantita-
tive result the day before. We had an estimation.

Q. You wanted to achieve if it
was possible an exact reading on that sample?

A. Right.

Q. And, Doctor, you have indicated
then when Dr. Mounstephen telephoned you he had



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informed you that there had been another death on
the cardiology ward?

A. Yes.

Q. I take it then that you were
aware on the basis of your discussion with
Dr. Mounstephen that the child had already died and
the likelihood therefore was that the sample that
would be received in the lab would be postmortem
samples?

A. I think that was the case, yes.

Q. Did you have any understanding
at that time as to whether you would in addition be
receiving a sample, an antemortem sample for digoxin
assay? Or do you recall?

A. I can't recall.

Q. Or could you look - perhaps
you could keep that book open at the page at which
it is now open but turn if you would to Exhibit 32A,
the other volume of documents, and Tab 36.

A. Yes.

Q. Doctor, this appears to be
another clinical chemistry requisition form. This
time with respect to Specimen No. J05491.

A. Right.

Q. And it bears the name of Justin



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Cook on the top right hand side of the page. Do you see that?

A. Yes.

Q. And it appears to have been signed by Dr. Mounstephen?

A. Right.

Q. Doctor, there are a number of day and time entries immediately above the doctor's signature. This appears to be the 22nd day and the month is indicated as a 2 and the hour is 4:30 a.m.

Do you see that?

A. Yes.

Q. Are the entries in that section of the requisition form insofar as you are aware, Doctor, intended to record the time and the day at which the sample was taken?

A. That is the intention, yes.

Q. And if we look to the date and time stamp that appears on this requisition form we see that the sample appears to have been received by the biochemistry laboratory at 6:05 in the morning of March 22nd.

A. Right.

Q. Doctor, the medical record of Justin Cook suggests that the time of death of the



F6 1
2 child was 4:56 a.m. in the morning. If that be so
3 and the time entry for the taking of the specimen as
4 disclosed on the requisition form is accurate at 4:30,
5 I take it we can agree that would appear to be an
6 antemortem sample.

7 A. It would appear to be an ante-
8 mortem sample. The only hesitation I have is that
9 that was the night that the clocks went forward an
10 hour, so that --

11 THE COMMISSIONER: In March?

12 THE WITNESS: If Dr. Mounstephen -
13 as I recollect.

14 THE COMMISSIONER: When did the
15 clocks go ahead in March?

16 MR. STRATHY: They spring forwards;
17 fall back.

18 THE COMMISSIONER: No, no, they
19 don't go forward in March, they go forward in April,
20 don't they?

21 THE WITNESS: Is it in April? I
22 thought it was in --

23 THE COMMISSIONER: I have had a
24 great many Aprils and Novembers in my day. So it is
25 October I guess. It is next week, isn't it? It
is not March, is it?



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MS. CRONK: Leaving aside the issue
of when the --

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THE COMMISSIONER: No, no. It is
not very often that I can demonstrate expertise but
certainly on losing hours, you don't lose them in
March, or maybe during wartime. There was no war on.

8

9

10

THE WITNESS: Well, I don't want to
argue with you. I thought - that was my recollection
and if I am wrong I am wrong, but that is my
recollection and I will stay with my recollection.

11

12

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MS. CRONK: Mr. Commissioner, I'm
sorry, I can't help you with whether or not the
clocks were moved forward an hour on March 21st, 1981
but surely that is not a difficult matter for us to
check.

16

17

18

THE COMMISSIONER: That happens to
be the vernal equinox but that has nothing to do
with the time - is that what you are thinking of?

19

20

21

22

THE WITNESS: No.

THE COMMISSIONER: Well the great
thing about being a Commissioner, judges have to be
ignorant but Commissioners can know that sort of
thing. All right.

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MS. CRONK: Q. Doctor, if that be
the case, and I assure you with a limited amount of



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future evidence, Mr. Commissioner, perhaps we can demonstrate that one way or the other, but if that be the case are you suggesting then that samples may have been taken at 5:30 a.m.?

A. Yes, if that error had occurred.

Q. All right. And if that be so, Doctor, and if the medical record of the child indicates that the arrest occurred at I believe it is 3:30 - 2:30, and the child died at 4:56 a.m., I take it you are suggesting that we should similarly move those entries forward as well so that the arrest should be 3:30 and the death 5:56 in the morning.

A. If similar --

THE COMMISSIONER: I think this is getting more and more ridiculous as times goes on, this whole line - yes, Miss Chown, do you have a solution?

MS. CHOWN: Yes, Mr. Commissioner, if I may be of assistance: my recollection, the time change occurred the night that Baby Gary Murphy died. I am just looking for my chart --

MS. CRONK: And that is April.

THE WITNESS: So that may be where I get --



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MS. CHOWN: And Dr. Soldin was involved as I understand with testing in that particular death and it may be that he has --

THE COMMISSIONER: This is the baby that died this year?

MS. CHOWN: Yes, that is correct.

MS. CRONK: In April of this year, sir, which suggests that it is April --

THE COMMISSIONER: That baby died the same day the Commission or the day after this Commission was appointed which was at the end of April, 1983.

MS. CHOWN: This may or may not be a red herring but if that is any assistance to Dr. Soldin that may solve it for the moment.

MS. CRONK: Q. Doctor, then to repeat my question, if --

THE COMMISSIONER: Please don't. Don't. Don't even suggest it. I know perfectly well that they weren't moving any clocks on the 21st of March, 1981.

MS. CRONK: Q. If the sample was taken at 4:30 in the morning, Dr. Soldin, and the child died shortly thereafter, I take it we can agree that was an antemortem sample if that is the case.



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THE COMMISSIONER: We can't even do that because unfortunately the child was in cardiac arrest before 4:30 so we can't. We can't - you see, it's a question. It is in God's hands when the child died. The child had cardiac arrest and was never resuscitated.

MS. CRONK: Well then --

THE COMMISSIONER: They pronounced it dead.

MS. CRONK: Well then to be fair to Dr. Soldin, and I take your point, Mr. Commissioner: did you have any understanding at the time you were supervising these assays as to whether or not any of them were antemortem samples one way or the other? Did you have any understanding?

THE WITNESS: No, I didn't.

MS. CRONK: Q. All right, fair enough, Doctor.

Then, Doctor, if we look at the entries which in fact appear on page 30 of Exhibit 32B, the first sample referred to is also the one referred to in Dr. Mounstephen's requisition form that we just looked at. That is Sample No. JO5491.

A. Correct.

Q. Again the reference indicates



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that the sample was taken on March 22nd and again at 4:30 a.m., and that assay appears to have been run neat with the result of greater than 5?

A. Right.

Q. Doctor, the same sample, and please correct me if I am wrong, appears to have been reassayed then at a dilution of times 2; this time with a result of greater than 10 nanograms?

A. Yes.

Q. Right. And similarly it was reassayed for a third time at a dilution of times 10 with a result of greater than 50.

A. Right.

Q. And then finally it was reassayed this time at a dilution of times 20 with a result of 72 nanograms?

A. Yes.

Q. Right.

Doctor, did you personally perform that assay and the others which are reflected on this page or were they performed under your supervision by the technician whom you had contacted by telephone?

A. They were performed by Mladen, yes.

Q. Under your supervision?



FF12

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A. Under my supervision, yes.

3

Q. And Doctor, we see as well

4

reference to a number of other samples which I will

5

come to in a moment, but can you help me first:

6

were all of these assays conducted at the same time

7

or were they run quite separately at different times

8

during the course of the day?

9

A. Are you talking about the ones
on the left hand side of this page?

10

Q. I am.

11

A. Yes, all run at the same time.

12

Q. All right. The next sample

13

then referred to, Doctor, is sample JO5490.

14

That appears to be a sample taken at
6:00 a.m. on March 22nd.

15

A. Yes.

16

Q. And the next sample is JO5479.

17

That appears to be a sample taken at 7:00 a.m.

18

A. Right.

19

Q. On the same day, and then

20

finally, JO5480 taken at 7:00 a.m.

21

If we could deal with the second sample,

22

Doctor, we see there there is an indication that it

23

is postmortem blood written in in handwriting on the

24

left hand side of the page.

25



FF13

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A. Yes.

3

Q. Doctor, in the requisition

4

form which, and I will be glad to direct you to it

5

if you wish, on the requisition form which applies

6

to the same sample number there is handwritten nota-

7

tion that it is postmortem blood, and I take it

8

if that information was disclosed in a requisition

9

form that is the source of the information which

10

appears in the digoxin book.

A. Right.

11

Q. All right. And, Doctor, with

12

respect to the results of the assays conducted on

13

that sample would I be correct in interpreting the

14

entries to mean that it was a first run neat with

15

the results greater than 5 nanograms?

A. Yes.

16

Q. It was then diluted at a

17

dilution of times 2 with a result of greater than 10?

18

A. Yes.

19

Q. Diluted at times 5 with the

20

result of greater than 25 nanograms?

A. Right.

21

Q. Diluted at times 10, reassayed

22

with the result of greater than 50?

23

A. Yes.

24

25



ANGUS. STONEHOUSE & CO. LTD.
TORONTO, ONTARIO

Soldin, dr.ex.
(Cronk)

1330

FF14

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Q. And then diluted again at
a dilution of times 20 with the result of 68 nanograms?

A. Yes.



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Q And it would appear, I take it, Doctor, there is no controversy that was the postmortem sample?

A. Right.

Q And Doctor, in summary then with respect to that specimen it appears that a minimum of four dilutions were required to obtain an exact reading and ultimately that exact reading was proven to be 69 nanograms?

A. Yes.

Q Doctor, we have seen that on the same day you had, as a result of your technicians' re-assaying of the Allana Miller sample, you had been informed as to a postmortem level of 78 on that sample?

A. Yes.

Q And we now have a 68 nanogram reading on a postmortem sample from Justin Cook?

A. Yes.

Q I take it that those two readings separately were the highest readings that you had ever seen in respect of a digoxin assay result?

A. Yes.

Q Doctor, with respect to the assays that were conducted on the two Justin Cook specimens, the first that I referred you to J050491,



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and the second, which is the postmortem sample, J05490, after those assays were completed and all of the assays on the various dilutions were completed, did you then take the opportunity to review the methodology that had been employed by the technicians involved and the results to determine whether or not the assay had been performed correctly?

A. Yes.

Q. And what were your conclusions with respect to those two specimens and those assays?

A. I thought they had been appropriately performed, yes.

Q. Doctor, we see as well a third sample with reference to Justin Cook, and it seems to apply to IV fluid, that is the indication on the left-hand side of the page, do you see that?

A. Yes.

Q. And that appears as well to be the case with the fourth specimen IV fluid?

A. Yes.

Q. Can you tell me, Doctor, how it happened that specimens of IV fluid were tested with respect to Justin Cook for digoxin, how did that come about?

A. Well, one of the possibilities



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is and was that digoxin could have been present in the IV fluid, and therefore we wanted to measure its concentration in that IV fluid that could have been administered.

Q. Had you requested during the course of your discussion with Dr. Mountstephen that specimens of IV fluid be provided for testing?

A. That is correct. I think this occurred as a result of discussions which I had with Dr. MacLeod the day before.

Q. Regarding Allana Miller?

A. Regarding Allana Miller which, you know, we wanted to check every possibility. So one of the possibilities was that the IV fluid might contain digoxin.

Q. And was it your understanding that the IV fluid that was supplied and that was then subsequently assayed; it appears first of all that there was two different specimens; do I have that correctly?

A. That is right, yes.

Q. And was it your understanding that that was IV fluid in each case that had been in use with respect to Justin Cook?

A. That was my understanding, yes.



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Q And Doctor, with respect to the first specimen of IV fluid that was assayed, we see that it was assayed first neat, and then on three separate dilutions; a dilution of 2, a dilution of 10 and a dilution of 20.

A. Right.

Q Do I have that correctly so far?

A. Yes.

Q And in each case the results appeared to be under .2 nanograms?

A. Yes.

Q And similarly the second specimen of IV fluid was again assayed four times neat, and on three dilutions of times 2, times 10 and times 20 and identical results were achieved?

A. Right.

Q Under .2 nanograms?

A. Yes.

Q What did those results, Doctor, if anything, signify to you?

A. Well, they ruled out the possibility that digoxin had been administered in the IV fluid.

Q Those results then indicated to you that because it was under .2 that there was no



GG.5

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digoxin which was measureable in those samples?

3

A. Yes.

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THE COMMISSIONER: I am sorry, how
do they rule them out because it is not in the IV fluid,
this is the IV fluid that is on its way from the bag
or the sac?

7

8

THE WITNESS: Yes.

9

THE COMMISSIONER: Down to the child?

10

THE WITNESS: Yes.

11

12

THE COMMISSIONER: Because they are
not in there now, how does it rule it out? I mean
when it is fed to the child earlier?

13

14

THE WITNESS: Well, if you add
something to a fluid in a bag it is going to mix
equally and then if you still have some ---

15

16

THE COMMISSIONER: Yes, but if you
add it on the way down?

17

18

19

THE WITNESS: If you add it to the
line that is a different story. We are talking about
the IV fluid in the IV bag.

20

THE COMMISSIONER: I see.

21

22

THE WITNESS: If you add it to the
line I agree with you.

23

24

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MS. CRONK: Q. Doctor, I take it on
the basis of the answers you have given to the



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Commissioner that it was your understanding that both of these specimens were specimens of IV fluid in the bag at the top of the IV apparatus?

4

5

A. Right.

6

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Q. I take it that you did not personally obtain these specimens, but that they were provided to your lab by Dr. Mounstephen?

8

9

A. I think so, yes.

10

11

Q. Doctor, with respect to the first IV sample, I would ask you to turn to Volume 32A, and turn to Tab 38 if you would. Do you have that, Doctor?

12

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A. Yes.

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Q. Tab 38; Doctor, this again appears to be a clinical chemistry requisition form that applies to Specimen J05479, and if we refer from that to the IV specimens recorded in the digoxin book that appears to be the first IV fluid specimen which was assayed, at least it bears the same sample number?

19

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A. Yes.

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Q. And in respect of this requisition form, it indicates that a number of requests were being made; the first, one of the three requests made was for a digoxin level; another request for an insulin level; and then we see "?" and the word "Isuprel".



GG.7

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A. Yes.

3

Q. Can you tell us what that

4

refers to, Doctor?

5

A. Well, it is a drug used fairly

6

frequently on the cardiac ward, Isuprel, so there isn't
an assay available to my knowledge in Toronto for that
drug.

7

8

Q. Was there at this time, Doctor,

9

in The Hospital for Sick Children, an assay available
for that drug?

10

11

A. No, not for Isuprel and there

12

still isn't.

13

Q. Doctor, if we look at the right-

14

hand side of the page the name of Dr. Jedeikin appears
in what appears to be a printed form over the name of

15

the physician and then immediately above that the

16

entry "IV fluid" and the entries on the photocopies

17

that were made are slightly cut off. In checking the

18

original the entries appear to be Isuprel and then

19

it is, is that microgram, mg?

20

A. It looks like milligram.

21

Q. Milligram?

22

A. Yes.

23

Q. And the original requisition

24

form, Doctor, shows per 100 cc's, can you help us as

25



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to what those entries would mean to you?

3

A. That would be the expected

4

concentration of Isuprel in that IV fluid.

5

Q. And Doctor, is Isuprel a normal

6

constituent of IV fluid as far as you are aware?

7

A. No, it isn't.

8

Q. Doctor, I would ask you as well

9

to turn to the very next tab in this book, Tab 39.
This is a clinical chemistry requisition form bearing

10

the same sample number, JO5480, as a second sample of

11

IV fluid that was provided to the lab and tested on

12

March 22nd. In this case we see a request for a

13

number of levels to be taken. The first is insulin;

14

the second is digoxin; and the third appears to be

15

Inderol?

A. Right.

16

Q. Do I have that correctly?

17

A. Yes.

18

Q. And although there is no

19

signature of a physician on this page, Doctor, we see

20

again the indication of IV fluid on the right-hand

21

side of the page?

A. Yes, right.

22

Q. There is no indication on this

23

sample, Doctor, of Isuprel or a request for an assay

24

on Isuprel?

25



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A. No.

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Q. Do you know, Doctor, whether or not any was believed to be contained in that specimen as well as in the former specimen of IV fluid?

5

6

A. I don't know, no.

7

8

9

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Q. And then, Doctor, on page 30 of the digoxin book that we were looking at a moment ago, immediately below the results for those two IV fluid specimens, we see reference to Control C, a level of 2.8 nanograms?

11

A. Yes.

12

13

Q. Was that one of the controls that was used in respect of the assays conducted on these specimens from Justin Cook?

14

A. Yes.

15

16

Q. And the other two are Control A and Control B set out as Items 1 and 2 on that page?

17

A. Yes.

18

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Q. Doctor, on the right-hand side of the page under the further entries for assays conducted on Sunday, March 22nd, we see reference to a further sample, Sample No. D57978 which, if I am reading the entries correctly, it is suggested was taken at 12:46 in the afternoon on March 22nd; do you see that, Doctor?



GG.10

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A. Yes.

3

Q. I would ask you to turn to Tab

4

41 of Volume 32A, the other volume in the document,

5

Tab 41, Doctor.

6

A. Right.

7

Q. Again, Doctor, another clinical

8

chemistry requisition form and this one bears the same

9

sample number as the sample that we have just looked

at, D57978.

10

A. Yes.

11

Q. In this case however, in the

12

space provided for the entry of the hour at which

13

the specimen was taken and the date upon which it was

14

taken, there appears to be in the hour column the

indication "8", do you see that?

15

A. Yes.

16

Q. And if we look at the date and

17

the time stamp which appears on the requisition form,

18

and it is difficult to read because there is hand-

19

writing that appears above it, but I take that to read

20

that the sample was received on March 22nd, 1981, in

the laboratory at 12:46 in the afternoon?

21

A. Right.

22

Q. Can we agree then, Doctor, that

23

in the entries in the digoxin book it would appear that

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the time that the sample was received by the laboratory was 12:46 in the afternoon, and that is the time it was then transcribed through into the digoxin book as opposed to the time at which the sample was taken?

7

A. Yes.

8

9

10

Q. And Doctor, with respect to the results of the assays conducted on that sample, we see that it appears to have been assayed first, I am sorry, neat, with the result of greater than 5 nanograms?

11

A. Yes.

12

13

14

15

Q. And then if we look at Item 29 on the same page, Doctor, we see it was assayed again on the same day at a dilution of times 10, and this time the result is indicated to be greater than 100 nanograms; do you see that, Doctor?

16

A. Yes.

17

18

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Q. And if we turn to the immediate next page, page 32 of the digoxin book, Doctor, it appears to have been assayed again at a dilution of times 20, again on the same day, March 22nd, and this time again the result of greater than 100 nanograms was produced; am I reading those entries correctly?

22

A. Yes.

23

24

25

Q. Doctor, were those assays in



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respect to that sample as well performed under your supervision?

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A. . They were, yes.

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Q. This appears, Doctor, to be a second postmortem sample taken in respect of Justin Cook, having regard to the requisition form that we have just looked at, it bears an indication that it is digoxin blood and the requisition form bears an autopsy number. I take it then as these assays were conducted under your supervision you were aware that two postmortem blood specimens had been brought to the lab for assay purposes on March 22nd, is that correct, Doctor?

13

14

A. Right.

15

16

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Q. And Doctor, with respect to the results of 100 nanograms, were the assays in respect of that sample conducted at the same time as the other specimens were assayed on March 22nd, or was that a series of assays that was conducted later that day?

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A. That was conducted later, in the late afternoon of that Sunday together with all the other patients on Wards 4A/B.

Q. So if we examine the rest of the entries on pages 31 and beginning of page 32, Doctor, would those entries then involve digoxin



GG.13

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assays conducted on the other patients from 4A and 4B?

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A. Yes.

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Q. Doctor, once the results of the various assays conducted on the specimens from Justin Cook, and I am referring now to the first specimen which I suggested to you was an antemortem specimen and the two postmortem specimens and the IV fluid specimens, once all those assays had been completed, did you then report the results of those various assays to individuals in the Hospital?

11

A. Yes, I did.

12

13

Q. And to whom did you report those results?

14

A. Well, to the same people I have mentioned before.

15

16

Q. In this case again we are talking about Dr. Carver, Dr. Goldberg and Dr. MacLeod?

17

A. Yes.

18

19

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Q. And were the results of the final postmortem samples with a level of greater than 100 reported as well to Dr. Costigan?

21

A. I am sure they were.

22

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Q. Doctor, were you aware on Sunday, March 22nd, at the time of performing these assays that Justin Cook was not known to have received digoxin at The Hospital for Sick Children?



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A. I can't answer that for sure. I could have been told that by Dr. Costigan.

Q. But sitting here today that is something that you can't specifically recall?

A. No, I can't recall, no.

Q. All right. Doctor, other than these particular specimens which were assayed, did you have any involvement in the testing of any other specimen, be it a blood specimen, a body fluids specimen or a tissue specimen from the body of Justin Cook?

A. No.

Q. All right. We have seen, doctor, in the case of Allana Miller that you felt it appropriate and indeed proceeded to arrange for a sample of digoxin elixir to be tested and for a digoxin assay to be run on the oral medication. That doesn't appear to have been done in respect of a similar sample from the ward on which Justin Cook died. Was there any particular reason for that?

A. I'm sure this was discussed with the clinicians involved and the reason must be that Justin Cook wasn't supposed to be on digoxin at all.

Q. I would have thought so,



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Doctor. Doctor, as well, could you turn again to Exhibit 32A, the volume of exhibits I believe to your left. Could you look at Tab 11 if you would, please.

5

A. Yes.

6

Q. Do you have that, Doctor?

7

A. Yes.

8

Q. Doctor, once again, it

9

is another clinical chemistry requisition form. It relates to Sample No. D57980 and it appears to bear the signature of Dr. Taylor.

10

11

A. Yes.

12

Q. Do you see that?

13

A. Yes.

14

Q. It also bears the name

15

expressly of Justin Cook together with an autopsy number, A88/81. Do you see that entry, Doctor?

16

17

A. Yes.

18

Q. And as well on the bottom

19

left-hand side of the requisition form there is an entry in brackets indicating that it is a heart muscle specimen and that a digoxin level is being requested. Do you see that, Doctor?

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A. Yes.

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Q. All right. There is a

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date and time stamp appearing on that requisition form as well and, once again, Doctor, if I am reading it correctly, it suggests that that specimen was received in the Biochemistry Laboratory on March 22nd at 12:46 in the afternoon, the same time that the second post mortem blood specimen was received.

A. Right.

Q. Am I reading that correctly?

A. Right.

Q. Doctor, do you have any recollection of a specimen of heart muscle from Justin Cook having been received by your laboratory on March 22nd for assay purposes?

A. Well, I'm sure I must have. I wouldn't authorize measurement of digoxin, I'm sure I said store that sample.

Q. I'm sorry, I didn't hear what you said, Doctor. You are sure you would have said?

A. That sample should be appropriately stored but that we wouldn't assay it.

Q. Can you help me as to why you would have given those instructions, Doctor?

A. Because we don't measure



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tissue for digoxin.

3

Q. All right.

4

A. And we never have.

5

Q. I take it, Doctor, and you

6

may have answered my next question as well, and that is, whether or not you participated in or supervised the performance of any digoxin assays in respect of the heart muscle specimen from Justin Cook?

7

8

9

A. No, I didn't.

10

Q. All right, thank you,

11

Doctor.

12

Doctor, finally, I would ask you

13

to turn to Tab 40 of the same exhibit book, Exhibit 32A, Tab 40.

14

A. All right.

15

Q. That appears, Doctor, to

16

be a second copy of the same clinical chemistry requisition form on the same heart muscle specimen.

17

18

A. Yes.

19

Q. Do you have that, Doctor?

20

A. Yes.

21

Q. All right. And on the

22

back side of that requisition form, Doctor, there are two references; first, one to what I take to

23

be Denise Jeffers, do you see that?

24

25



1
HH5 2 A. Yes.
3 Q. Do you know who Denise
4 Jeffers is, Doctor?
5 A. No.
6 Q. All right. There also
7 appears to be a reference, it appears upside down,
8 it says "to endocron".
9 A. Yes.
10 Q. Do you recall seeing any
11 requisition form with respect to this heart muscle
12 specimen, Doctor, at the time these assays were
13 being performed?
14 A. I don't at this point in
15 time, no.
16 Q. I take it, Doctor, that
17 you can't help me with the meaning of that entry
18 either?
19 A. No.
20 Q. All right. Doctor, quite
21 apart from further specimens from the body of Justin
22 Cook, of whatever variety, did you at any time, be
23 it on March 21st or March 2nd or at any time there-
24 after, participate in, and by that I mean conduct or
25 supervise the performance of any digoxin assays on
any body fluid specimens or tissue specimens from any



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child who died on Wards 4A/4B in the period July 1980 to March 1981?

A. No.

Q. All right. And similarly, Doctor, other than the digoxin assays concerning Allana Miller that we have examined and the assays concerning Justin Cook that were performed on the 22nd of March, did you participate in, by way of actually conducting or by way of supervising, the conduct of any digoxin assays on any specimens taken from any other child, including blood specimens, who died on Wards 4A or 4B during the period of time with which we are concerned?

A. No.

Q. All right. Doctor, finally, during the course of your experience in conducting digoxin assays at The Hospital for Sick Children during this time period when you were on call, whether it be over the evening shift or the weekend and during your experience subsequently when your laboratory assumed responsibility for these digoxin assays, have you ever had occasion to send a specimen to Mount Sinai Hospital for the purposes of a digoxin assay at that hospital?

A. I cannot recollect ever



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having sent a sample.

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Q.

All right. Doctor, were

you aware that a portion of a blood specimen from
the body of Kevin Pacsai had been sent to Mount Sinai
Hospital for digoxin assay purposes?

A.

Subsequent to all this,
yes.

Q.

All right. I take it then
that you didn't become aware of that fact until
after the events of the weekend of March 21st and
March 22nd?

A.

Correct, yes.

Q.

And, Doctor, with respect
to that particular issue can you help me as to when
you did become aware of the deaths of Kevin Pacsai
and Janice Estrella and the digoxin levels that had
been recorded at the Hospital with respect to those
two patients? When did you first become aware of
those facts?

A.

My recollection is that
that occurred on the Monday; that's my recollection.

Q.

That would be the Monday
after the conduct or the supervision by you of the
assays on Justin Cook's specimens?

A.

Yes.



HH8

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Q. Monday, March 23rd?

3

A. Yes.

4

Q. All right. Doctor,

5

finally, on March 22nd, the Sunday when you were

6

supervising the assays from the specimens on Justin

7

Cook, do you have any recollection of Dr. Richard

8

Rowe attending at the laboratory where those assays

9

were being run to obtain the results of various

10

digoxin assays that had been run on Kevin Pacsai,

11

Janice Estrella, Allana Miller and then Justin Cook?

Do you have any recollection of that?

12

A. No, I don't.

13

MS. CRONK: All right. Thank you,

14

Doctor. I have no further questions, Mr. Commissioner.

15

THE COMMISSIONER: All right,

thank you. Mr. Grant.

16

MR. GRANT: Excuse me, Mr.

17

Commissioner, just one second.

18

Sir, we have no questions.

19

THE COMMISSIONER: Thank you. Is

20

this your client, Miss Chown?

21

MS. CHOWN: No, he isn't, Mr.

Commissioner.

22

THE COMMISSIONER: Oh, all right.

23

Mr. Strathy?

24

25



HH9

CROSS-EXAMINATION BY MR. STRATHY:

Q. Doctor, near the end of your evidence you mentioned that a heart muscle specimen had been submitted to your laboratory. Now, is it your recollection that you instructed your staff not to test that sample?

A. I wish I could have more than a vague recollection for you because it is many years ago. But I think that that is what occurred, yes.

Q. And I take it your recollection then is vague on that point?

A. Right.

Q. But whatever the case, do I understand that up to that point you had not tested tissue for digoxin in your laboratory?

A. That is correct, yes.

Q. There was no procedure for it in your laboratory?

A. That's right.

Q. And subsequent to that time you did not test tissue for digoxin, is that so, at least on a regular basis?

A. We are currently looking at some tissues but that is a research project which



1
HH102 isn't connected -- well, not connected to these
3 tissues that you are talking about.

4 Q. Well, at least on a
5 regular basis for the purposes of your therapeutic
6 monitoring program you did not test tissue?

7 A. That is correct.

8 Q. And the research that is
9 going on at the moment, is that the research that
10 Dr. Phillips is doing?

11 A. It is together with Dr.
12 Phillips, yes.

13 Q. Now, you mentioned, I
14 believe it was in connection with the Miller sample,
15 that one of the concerns that you had at the time
16 was with respect to the specificity of the test,
17 am I right?

18 A. Yes, correct.

19 Q. And by that you mean
20 whether or not the test is in fact measuring digoxin?

21 A. Yes.

22 Q. Or measuring the presence
23 of digoxin in the sample?

24 A. Right.

25 Q. And do I understand
correctly that was a concern you had at that very time?



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A. I think it has to be of concern with every analysis. Yes, it was a concern that I had at that time too.

Q. Well, is it still a concern that you have, that is, the specificity of the radioimmunoassay?

A. It is a much bigger concern today than it was three years ago.

Q. Well, that is what I would like to ask you about, Doctor. Let me ask you why you say that. Why is it a much bigger concern today?

Doing this "in general" > 5 mos ago.

Not according to Seccombe's ex —
didn't find after few mos of age!
See Valdes article — measurable in
"adult controls".



A. Well, apart from the published

interferences in the digoxin assay and known chemicals which interfere, we have been ourselves in the last five months in particular looking at the interference of substance X. So, we have carried out many experiments purifying substance X and obtaining as much data on this compound as we can. But it is clear that this is an endogenous compound, it is present in other words in all of us. It gets excreted in the urine when any one of us takes a water load. So, by a water load I mean if we drink quite quickly a litre of water then substance X will be excreted in the urine. Evidence of this type is in the literature already, it has been published by many people such as Drs. Gault, Dr. Valdes and we have repeated their work. We have found it to be reproducible. In other words, we can also isolate substance X from urine after people have been subjected to a water load. We have purified this compound to a considerable extent. We have done a mass spectrum on it now. So, we have quite a lot of information about it.

It is clear therefore that there are endogenous materials that cross react in the digoxin assay.



3-2 1
2 Now, these materials are of considerable
3 concern when one is trying to measure digoxin.

4 Q. Well then, are you telling us
5 that your research in the last five months has confirmed
6 that there may be something, let's be specific, in
7 the blood of infants that reacts like digoxin under
8 the radioimmunoassay test.

9 THE COMMISSIONER: I thought he said
10 it was in the blood of every one.

11 MR. STRATHY: Well, he has talked about
12 in the urine.

13 A. I have talked about in the
14 urine because this material seems to be cleared
15 renally quite effectively. Dr. Valdes in St. Louis,
16 Missouri has found it in the blood of patients with
17 renal failure. So that when the kidneys do not
18 excrete it adequately then your serum concentrations
19 do appear to increase.

20 In premature infants again you would
21 often have premature renal function or poor renal
22 function and therefore again you might expect the
23 concentration to increase. In fact, that is where
24 one has seen it. One has seen it in the premature
25 group and one has seen it in patients with renal
failure.



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2 But it is difficult to purify from
3 serum because one cannot exsanguinate these individuals.
4 But one can easily carry out water load studies and
5 obtain this material by that route.

6 THE COMMISSIONER: Have you done these
7 studies on blood as well or just on urine?

3-3
8 THE WITNESS: We've looked at the
9 blood concentrations or the serum concentrations
10 of substance X under conditions of a water load in
11 normal individuals and the serum concentrations do
12 not increase. They do not appear to be measurable.
13 Now, if you are using the digoxin assay as the criteria
14 of measurement, in other words, as soon as this
15 material, whatever it is is released it gets excreted
16 renally provided you have adequate renal function.

17 Q. Well, you have suggested I
18 gather that some premature infants may not have
19 adequate renal function?

20 A. Correct.
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Q. And would it also be the case that infants, some infants, at least with congestive heart failure may also not have adequate renal function?

A. Yes.

Q. So would you not also expect to find this substance in infants with congestive heart failure?

A. You may.

THE COMMISSIONER: Where, though? Where would you find it? Would you find it in the serum or would you find it in their urine or where would you find it? Or would you find it in their kidneys?

THE WITNESS: This is conjecture. We haven't looked in the urine of patients with heart failure. That is something we have to do but it is excreted in the urine of every person we have looked at so far, every normal individual, and I would be surprised if it wasn't excreted in the urine of our sick individuals as well.

Q. All right. Just to be clear, this again - have you done radioimmunoassays on the blood serum from the individuals you have been talking about or have you done it on urine?

A. We have done it on both blood



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2 and urine in normal individuals.

3 Q. And you found this substance
4 X in the blood of normal individuals in the circum-
5 stances you have described?

6 A. No. We found it in the urine
7 because these people have normal renal function.

8 Q. All right.

9 A. As soon as the renal function
10 deteriorates there are other reports of it being
11 present in the blood.

12 Q. All right. And this research
13 that you have been talking about, Doctor, is it
14 research that has been ongoing let us say since you
15 last gave your evidence here?

16 A. Yes.

17 Q. I can't remember, Doctor, when
18 was it you last gave your evidence here?

19 THE COMMISSIONER: I think it was ---

20 MS. CRONK: June.

21 THE WITNESS: June.

22 MR. STRATHY: Q. So it has been going
23 on now for four or five months?

24 A. Correct, yes.

25 Q. And it started in June?

A. Yes. It started quite



1
2 seriously in May and it has picked up momentum ever
3 since.

4 Q. So that you are in the race
5 to isolate and analyse substance X, are you?

6 A. I believe we have isolated
7 substance X. I believe we have a mass spectrum on
8 substance X. Evidence appears to be that it is
9 pure, that we have isolated a pure compound.
Evidence that we have isn't ---

10 THE COMMISSIONER: If - sorry, I
11 don't want to interject. I want you to be able to
12 go on, but if there is renal failure in an infant or
13 in an adult, are you suggesting that you may then find
14 some evidence of this substance X, this endogenous
material in the serum?

15 THE WITNESS: Yes.

16 THE COMMISSIONER: But you haven't
17 found it?

18 THE WITNESS: I haven't looked in
19 patients with renal failure.

20 THE COMMISSIONER: There must be
21 millions of people with renal failure.

22 THE WITNESS: There are a lot of
23 people with renal failure and there are a lot of
24 reports on the substance X in their plasma, yes.
25



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2 THE COMMISSIONER: To what extent is
3 this renal function? Is there some kind of report -
4 I don't want you to just ---

5 THE WITNESS: You should refer to the
6 work of Valdes in particular at St. Louis, Missouri.
7 He works at the Jewish Hospital in St. Louis. I can
8 provide copies of his papers if you wish.

9 THE COMMISSIONER: Well

10 THE WITNESS: He has found it in a
11 lot of patients with renal failure; described it there.
12 He has also carried out ---

13 THE COMMISSIONER: How is substance
14 X in babies, you know, without renal failure at all.
15 Babies who never had digoxin have shown a digoxin
16 level, appreciable digoxin level. We have had that
17 evidence from the beginning.

18 THE WITNESS: They may have had
19 immature renal function, though.

20 MR. STRATHY: Q. So what you are
21 telling us, Doctor, is that a baby who has never had
22 digoxin at all may show up as having "digoxin" in
23 his system under a radioimmunoassay procedure?

24 A. Yes.

25 Q. When in fact it is really not
digoxin at all: it is substance X?



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2 A. Correct.

3 THE COMMISSIONER: We have had that.
4 We have had that evidence. What I am trying to find
5 out is what additional evidence are you giving us now?
6 What are you telling us? Are you saying that adults -
7 sorry, Mr. Young, did you want to ...

8 MR. YOUNG: I was just going to point
9 out, Mr. Commissioner, that the article the Doctor was
10 referring to is our Exhibit No. 9.

11 THE COMMISSIONER: Yes.

12 MR. YOUNG: I believe that was the
13 article prepared by Dr. Valdes.

14 THE COMMISSIONER: That is Exhibit 9,
15 you say? Yes, I see.

16 Have you read this - I guess you have.
17 It is June, 1983.

18 THE WITNESS: Yes, I am sure I read
19 it at some point.

20 THE COMMISSIONER: Have you anything
21 further, though, that you can tell us about - what
22 I am really interested in, of course, either with
23 or without renal failure this substance could get
24 into the serum and to what extent of these babies,
25 that is all. If it is likely to affect these readings
I would be interested in it, and if it is not likely

Which "clinical conditions" have never
occurred since March 22/81 so as
to produce pm levels of 72, 78?



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2 to I am not.

6 3 THE WITNESS: Well, you are asking a
4 very difficult question and I don't have an answer
5 for you.

6 All I can say is it does obviously
7 get into the serum. It hasn't been measured or given -
8 it hasn't provided digoxin measurements anywhere near
9 the values which we have been dealing with in these
10 particular patients on 4A/B, and so there is a missing
11 step here. How can one - is it possible that it will
12 be released under certain conditions in large enough
amounts to provide these sort of concentrations?

13 MR. STRATHY: Q. Well ---

14 A. It is possible that that could
15 happen under certain clinical conditions, but I can't
16 tell you, you know, what they are, and we are actively
looking at this.

17 Q. But, Doctor, then is what you
18 are telling us that the high levels that we are seeing,
19 postmortem levels of 72 or 100 that we are seeing in
20 these infants after death of digoxin in their serum
21 may be explained, now I simply put it at may be
22 explained by the presence of some endogenous substance
23 other than digoxin?

24 A. There is a chance that that
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could be, yes.

Q. And that is something that presumably your research is looking into at this time?

A. Right.

THE COMMISSIONER: You are heading for that but you have no evidence?

THE WITNESS: I have no ---

THE COMMISSIONER: The figures that we are talking about here - I don't know whether I am looking at the right chart.

THE WITNESS: Well, most people, and you can look at a dozen other investigators have found concentrations only up to around 4 for what they call substance X, so unless there is some clinical reason in these kids that would give rise to a further release of substance X it would be hard to explain away the 72s and the 78s.

MR. STRATHY: Q. Are you suggesting there may be a clinical reason?

A. Yes, there may be.

Q. Are you able to point us in any direction as to potential clinical reason that you would want to investigate?

A. Well, you would like to know what we are currently looking at, is that ---

(R)

Have done prev. dip levels on all
children who died on 4A/D since
Mch / 81.
Some have had degree of ~~some~~ dip hindlimb?
Some had had resuscitat- efforts
Defibrillation
ECR.



Q. Well ---

A. The situations that we are
currently looking at are children that had cardiac
arrests, that have had difibrillation treatment, that
have had shock treatment, that have had massive
amounts of adrenaline given to them, that have been
given things like intralipid ---

Q. Given things like what?

A. Intralipid which is a form of
hyperelementation.

THE COMMISSIONER: What did they find?

MR. STRATHY: Q. I wonder ---

A. We are just starting that.
What you wanted to know ---

MR. STRATHY: I appreciate your help,
Mr. Commissioner. I have a few questions.

THE COMMISSIONER: Watch your language!

MR. STRATHY: Q. Doctor, these things
that you have mentioned, defibrillation and massive
amounts of adrenaline are things that we have heard
have occurred in resuscitation efforts. Is that right?

A. Yes.

Q. And do I take it you are look-
ing at the effect of those things on the possible
release or amplification of substance X in the blood



1
2 of children?

3 A. Yes.

4 Q. And is your research in this
5 area prompted by the very circumstances that this
6 Commission is looking at?

7 A. Yes.

9 MR. STRATHY: All right, thank you.

8 Mr. Commissioner, I am going to be a
9 while longer and I wonder if you might - I would like
10 to think about what the witness has said before I
11 ask him any more questions.

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THE COMMISSIONER: Yes. Well,
we will stand it down -- how much more research
will you do between now and ten o'clock tomorrow
morning, doctor?

All right. We will proceed then
at ten o'clock tomorrow.

MS. KITLEY: Before we rise for
the day, Mr. Commissioner, last Thursday when Dr.
Ellis was on the stand he indicated that he would
look for certain information and reply today and
I know Miss Cronk asked him about that and he was
unable to answer.

I understood him to say that the
answer might be in a computer printout but that he
no longer has these but the police has them.

Might we just have some sort of
an indication that those printouts will be sought
and if available be produced?

THE COMMISSIONER: I don't know
where I should be looking to.

MS. CRONK: I think in the first
instance it is over here, and I had indicated and
perhaps I should do so formally that we will make
every effort to find them.

THE COMMISSIONER: And if you can't



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2 you will speak to Mr. Young or someone about it,
3 will you?

4 MS. CRONK: That is where I will
5 look first.

6 MS. KITLEY: Thank you, sir.

7 THE WITNESS: I don't know if I
8 can make a request as well and that is we have
9 developed assays for the measurment of digoxin by
10 liquid chromatography as well as by mass spectrometry
11 that definitively show that this compound is digoxin
12 and cannot be anything else.

13 I would very much appreciate
14 receiving some of the samples on patients that have
15 values, elevated values, because we don't have these.
16 The police, of course, took them long ago as they
17 did everything. But those samples should surely
18 be checked out with liquid chromatography and mass
19 spectrometry to definitively establish the presence
20 of digoxin.

21 MR. HUNT: Is this high-pressure
22 liquid chromatography?

23 THE WITNESS: Yes.

24 MR. STRATHY: May I just ask one
25 question, Mr. Commissioner?

Q. Witness, are you suggesting



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II3.3 2 that with the procedure you have described you can
3 tell us whether the samples contain digoxin or
4 Substance X?

5 THE COMMISSIONER: If you can't,
6 you can tell us whether it is true digoxin? Is
7 that right?

8 THE WITNESS: If you have enough
9 material for assay, yes, I think that is true.

10 If you have enough material for
11 assay, I think we would be able to do a liquid,
12 a series of liquid chromatography runs followed by
13 mass spectrometry to definitively establish whether
14 or not digoxin is there.

15 THE COMMISSIONER: I don't know
16 what state they are in now or whether they are still
17 available or whether they are assayable.

18 MS. CRONK: It is a matter that
19 has not been raised for the first time by this
20 witness and it is a matter that we will discuss
21 further with counsel for the Hospital.

22 MR. STRATHY: It certainly seems
23 that if it can be done, it would be highly desirable
24 for everybody's purpose that it be done. It is hard
25 to imagine why if the request was made before it
hasn't been complied with.



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II3.4 2 MS. CRONK: Well perhaps, Mr.
3 Strathy, perhaps you jumped too quickly. When I say
4 it has been raised before, it has been in discussion
5 with Dr. Soldin that we recently learned of the
6 research --

7 THE COMMISSIONER: Well, it would
8 seem to me that everybody should be in on it if it
9 is going to be done under the auspices of the
10 Commission. It should be everybody, all the experts --
11 anybody who wants to have presence should be there.

12 MS. CRONK: I quite agree, sir. We
13 just don't know what is there, what is available,
14 if anything.

15 THE COMMISSIONER: Yes. That's the
16 first step to find out if anything is available to
17 be assayed. Once we do that rather than have it
18 done by one party and called back it should be done
19 by anybody who knows about it doing it at the same
20 time I would think so that you can have something...
21 rather than have you do it alone -- I don't know
22 who else we have besides Mr. Cimbura, have we, that
23 would be interested in this experiment?

24 MS. CRONK: Mr. Commissioner,
25 obviously if there are samples remaining, specimens
from any of these children that are available for



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assay at all then we will have to investigate the
circumstances under which they could be further
tested. We are just trying to find out whether there
are any.

THE COMMISSIONER: Yes. All right.

Did you want to say anything else?

THE WITNESS: No, just that if there
are samples available, please don't split them up
because we might need everything that is available
that is there to do just one assay.

THE COMMISSIONER: I wasn't thinking
of splitting them up. I was just thinking of
having everybody present and doing it at the same
time.

THE WITNESS: Doing it in front
of everybody?

THE COMMISSIONER: That is right.

All right, ten o'clock.

--- whereupon the hearing was adjourned at 4:45 p.m.
until Tuesday, the 18th day of October 1983,
at 10:00 a.m.

COMMISSIONER'S STATEMENT

PHAC
Read by SGMG.
10am. Tues Oct 18

Mr. Sopinka has raised two questions.

- (1) That no question should be put in evidence intended to elicit an answer indicating who committed an alleged crime, and
- (2) That the Police Report, that is the report of the Metropolitan Toronto Police referred to by the Attorney General in his report to the legislature, should be produced to him and presumably to other Counsel concerned.

As to (1), Mr. Sopinka concedes, as I understand it, that such evidence may be relevant for another purpose, namely to determine the cause of death. He asks, however, that before it is received some effort be made to explore how it can be done without implicating an individual.

I am sympathetic to his position and, particularly, am concerned about the unfairness it may cause a party if the evidence is adduced at a time when the opportunity to answer is to be long delayed. Nevertheless, I cannot make a blanket ruling for several reasons as follows:

- (a) I cannot know in advance of the evidence being tendered whether the evidence will be relevant to Phase I.
Each instance must be considered at the time it is tendered.

- (b) The problem is not yet resolved as to whether the Terms of Reference which require me to report on the cause of death permit me to express any opinion as to the complicity of any person in the deaths. As will be seen, I am suggesting that there be argument upon that question.
- (c) It is abundantly clear to me that the apparent complicity of Susan Nelles, at least up till the time of her release after the Preliminary Inquiry, is relevant to the determination of the issues in Phase II.

To prevent an injustice, not in the Commission but in the reporting of the proceedings in the media, I will certainly entertain any motion for immediate cross-examination or for evidence out of turn or for any other relief whenever a party's complicity is implied. I hope that will not be necessary but an example has already been demonstrated during the evidence of Dr. Fowler.

The second issue relating to the Police Report clearly is arguable. As the Counsel most concerned are Mr. Sopinka and Mr. Percival, I suggest that they agree upon some time, preferably at 3:45 in the afternoon and the argument can then take place. Of course it is open to Counsel to resolve the matter without argument.

There are two further matters which are not so urgent but I am satisfied must be resolved in the interests of a fair hearing. They are first the issue referred to above, namely whether I can in the Report if I should find that there was a deliberate overdose of Digoxin contributing to the deaths of any baby implicate any person in that overdose, or to put

it in Mr. Scott's words, ~~If~~ I can "name names". Secondly, some Counsel have suggested that evidence in Phase II should not include anything that occurred after the release of Susan Nelles at the Preliminary Inquiry. I think the problems lend themselves to written argument and I would ask any Counsel having an opinion on either matter to submit that written argument to me by November 1st, 1983. That argument will be distributed among all Counsel on that day and each Counsel will have an opportunity to reply by November 10th. I remind all Counsel that the essential question is what the Terms of Reference permit or require.

There is just one other matter I wish to raise at this time. Mr. Sopinka suggests that no finding of misconduct can be made against any person unless a formal notice of misconduct is given and presumably all the evidence given thereafter. I do not so interpret the section which calls only for reasonable notice of the substance of the misconduct alleged against him and full opportunity to be heard in person or by Counsel. I cannot imagine that there could ever have been the slightest doubt as to why each member of the Trayner team is here represented by Counsel funded by the Province. If such a doubt has ever existed, let me make it now quite clear that each of them may be found to be implicated either by accident or with deliberation in the deaths of the children. I emphasize that to date very little of such evidence has been presented but it is anticipated that some such evidence will be tendered and of course Counsel for the parties concerned will be entitled during the hearing to be heard and to adduce evidence relevant to the issues before this Commission.

